Policy Number	**SUR703.010**
Policy Effective Date	**5/7/2026**

Lung and Lobar Lung Transplant

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Related Policies (if applicable)
None

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Legislative Mandates

EXCEPTION: For Texas ONLY: For policies (IFM, Student, Small Group, Mid-Market, Large Group, fully-insured Municipalities/Counties/Schools, State Employee Plans, PPO, HMO, POS) delivered, issued for delivery, or renewed on or after January 1, 2024, TIC Chapter 1380 (§§ 1380.001 – 1380.003 [SB 1040 Human Organ Transplant]) prohibits coverage of a human organ transplant or post-transplant care if the transplant operation is performed in China or another country known to have participated in forced organ harvesting; or the human organ to be transplanted was procured by a sale or donation originating in China or another country known to have participated in forced organ harvesting. The commissioner of state health services may designate countries who are known to have participated in forced organ harvesting. Forced organ harvesting is defined as the removal of one or more organs from a living person by means of coercion, abduction, deception, fraud, or abuse of power or a position of vulnerability.

Coverage

Lung transplantation **may be considered medically necessary** for carefully selected individuals with end-stage pulmonary disease, including but not limited to, one of the conditions listed below.

A lobar lung transplant from a living or deceased donor **may be considered medically necessary** for carefully selected individuals with ESPD, including but not limited to one of the conditions listed below.

Examples of conditions associated with end-stage pulmonary disease:

- Alpha-1 antitrypsin deficiency,
- Bronchiectasis,
- Bronchiolitis obliterans,
- Bronchopulmonary dysplasia,
- Pulmonary hypertension,
- Chronic obstructive pulmonary disease,
- Cystic fibrosis (both lungs to be transplanted),
- Eisenmenger's syndrome,
- Emphysema,
- Eosinophilic granuloma,
- Idiopathic or interstitial pulmonary fibrosis,
- Lymphangiomyomatosis,
- Sarcoidosis,
- Scleroderma.

Lung or lobar lung transplantation, after a failed lung or lobar lung transplant, **may be considered medically necessary** in individuals who meet the criteria for lung transplantation.

Lung or lobar lung transplantation **is considered experimental, investigational and/or unproven** in all other clinical 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 individuals may be candidates for combined heart and lung transplantation

Individuals 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.

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/pulmonary 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 the Organ Procurement and Transplantation Network (OPTN) and United Network of Organ Sharing.

Lung Transplant
In 2024, 48,136 transplants were performed in the United States procured from more than 41,000 deceased donors and 6,900 living donors. (2) Lung transplants were the fourth most

common procedure with 3,339 transplants performed from both deceased and living donors in 2024.

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, alpha-1 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 COPD. Lung or lobar lung transplantation is an option for patients with ESPD despite these measures.

A lung transplant refers to single-lung or double-lung replacement. In a single-lung transplant, only 1 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 1 lobe obtained from each of 2 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 (LAS). (3) A score may range between 0 and 100 and incorporates predicted survival after transplantation and predicted survival on the waiting list; the LAS takes into consideration the patient's disease and clinical parameters. The waiting list incorporates the LAS, geography, and blood type classifications. Children younger than 12 years old receive 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.

Potential Contraindications to Transplantation

Malignancy

Malignancies are common after lung transplantation, with 21% and 40% of patients reporting 1 or more malignancies at 5 and 10 years post-transplantation, respectively. (4) Skin cancer occurred most frequently, and lymphoproliferative disorders were the malignancies most associated with morbidity post-transplantation.

Human Immunodeficiency Virus Infection

Current OPTN policy permits human immunodeficiency virus-positive transplant candidates. The 2020 U.S. Public Health Service guideline also allows for transplantations in HIV-positive recipients with proper screenings and effective regimens for HIV infections; it recommended that all transplant candidates receive HIV, hepatitis b virus, and hepatitis C

virus testing during hospital admission for transplant surgery. (5) In 2022, the U.S. Public Health Service published updated guidance for testing transplant candidates aged less than 12 years of age. (6) They recommended that children less than 12 years of age who have received postnatal infectious disease testing are exempt from repeat pretransplant HIV, HBV, and HCV testing during hospital admission for transplant surgery.

The British HIV Association and the British Transplantation Society (2017) updated their guidelines on kidney transplantation in patients with HIV disease. (7) These criteria for adding a patient to the waitlist may be extrapolated to other organs:

- Adherent with treatment, particularly antiretroviral therapy,
- Cluster of Differentiation 4 count greater than 100 cells/mL (ideally >200 cells/mL) for at least 3 months,
- Undetectable HIV viremia (<50 HIV-1 RNA copies/mL) for at least 6 months,
- No opportunistic infections for at least 6 months,
- No history of progressive multifocal leukoencephalopathy, chronic intestinal cryptosporidiosis, or lymphoma.

Other Infections

Infection with *Burkholderia cenocepacia* is associated with increased mortality in some transplant centers, a factor that may be considered when evaluating the overall risk of transplant survival. (8) Two articles have evaluated the impact of infection with various species of *Burkholderia* on outcomes for lung transplantation for cystic fibrosis. In a study by Murray et al. (2008), multivariate Cox survival models were applied to 1026 lung transplant candidates and 528 transplant recipients. (9) Of the transplant recipients, 88 were infected with *Burkholderia*. Among transplant recipients infected with *B. cenocepacia,* only those infected with nonepidemic strains (n=11) had significantly greater posttransplant mortality than uninfected patients (hazard ratio [HR], 2.52; 95% CI, 1.04 to 6.12; p=.04). Transplant recipients infected with *Burkholderia gladioli* (n=14) also had significantly greater posttransplant mortality than uninfected patients (HR, 2.23; 95% CI, 1.05 to 4.74; p=.04). When adjustments for specific species or strains were included, the LAS of *Burkholderia multivorans*-infected transplant candidates were comparable with uninfected candidate scores, and scores for patients infected with nonepidemic *B. cenocepacia* or *B. gladioli* were lower. In a smaller study of 22 patients colonized with *Burkholderia cepacia* complex who underwent lung transplantation in 2 French centers, Boussaud et al. (2008) reported that the risk of death by univariate analysis was significantly higher for the 8 patients infected with *B. cenocepacia* than for the other 14 colonized patients (11 of whom had *B. multivorans*). (10)

An analysis of international registry data by Yusen et al. (2016) found that non-cytomegalovirus infection is a major cause of mortality within 30 days of a lung transplant in adults. (11) A total of 655 (19%) of 3424 deaths after transplants between 1990 and 2015 were due to non-CMV infection. Only 3 (0.1%) of the deaths were due to CMV infection.

Regulatory Status
Solid organ transplants are a surgical procedure and, as such, are not subject to regulation by the U.S. Food and Drug Administration.

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. Solid organs used for transplantation are subject to these regulations.

Rationale

This policy is based on review of relevant professional association recommendations.

American Thoracic Societyet al.
Evidence-based recommendations from the ATS and 3 international cardiac societies were published in 2011 for the diagnosis and management of patients with idiopathic fibrosis. (12) For appropriately selected patients with idiopathic pulmonary fibrosis, the international guideline panel recommended lung transplantation (strong recommendation, low-quality evidence). An update to this document was published in 2015 in which the committee did not make a recommendation regarding single versus bilateral lung transplantation in patients with idiopathic fibrosis. (13) The committee stated that "it is unclear whether single or bilateral lung transplantation is preferential for long-term outcomes."

In 2022, the American Thoracic Society along with the 3 other international cardiac societies published updated guidance on diagnosis and management of idiopathic pulmonary fibrosis and progressive pulmonary fibrosis. (14) In terms of treatment considerations, the committee stated that "patients at increased risk of mortality should be referred for lung transplantation at diagnosis."

In 2014, the ATS published guidelines on the management of bronchiolitis obliterans syndrome in lung transplant recipients in conjunction with the International Society for Heart and Lung Transplantation and the European Respiratory Society. (15) The guideline recommends referral to a transplant surgeon to be evaluated for retransplantation for end-stage bronchial obliterans syndrome that is refractory to other therapies.

In 2025, the ATS published guidelines on interventional strategies for children with progressive pulmonary hypertension. (16) Recommendations made regarding lung transplantation are below:

- "We suggest lung transplantation in children with progressive PH [pulmonary hypertension] and RV [right ventricular] failure despite optimal therapy (conditional recommendation, very low certainty of evidence)."

- "We suggest lung transplantation in children with progressive PH and RV failure despite optimal therapy who are on ECMO [extracorporeal membrane oxygenation] support without reversible cause (conditional recommendation, very low certainty of evidence)."

International Society for Heart and Lung Transplantation
Initial Transplant
In 2021, the ISHLT published consensus-based guidelines on selection of lung transplant candidates. (17) The guidelines state that:
"Lung transplantation should be considered for adults with chronic, end-stage lung disease who meet all the following general criteria:
1. High (>50%) risk of death from lung disease within 2 years if lung transplantation is not performed.
2. High (>80%) likelihood of 5-year post-transplant survival from a general medical perspective provided that there is adequate graft function."

The guideline also notes risk factors to be considered in the evaluation of transplant candidates, along with pediatric and disease-specific considerations.

Retransplant
The 2021 guideline update briefly addressed lung retransplantation, with the consensus statement noting that "The outcomes after re-transplants are inferior compared to first lung transplants, particularly if the re- transplant is done within the first year after the original transplant or for patients with restrictive allograft syndrome [...] In the pre-transplant evaluation of such patients, particular emphasis should be focused on understanding the possible reasons for the graft failure, such as alloimmunization, poor adherence,
gastroesophageal reflux, or repeated infections." (17)

Medicare National Coverage
Lung transplantation is covered under Medicare when performed in a facility approved by Medicare as meeting institutional coverage criteria. (18) 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.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or

reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	32850, 32851, 32852, 32853, 32854, 32855, 32856
HCPCS Codes	S2060, S2061, S2152

*Current Procedural Terminology (CPT®) ©2025 American Medical Association: Chicago, IL.

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Centers for Medicare & Medicaid Services

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare & Medicaid Services does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at cms.hhs.gov.

Policy History/Revision	
Date	**Description of Change**
5/7/2026	New medical document. Lung transplant or lobar lung transplant may be considered medically necessary when criteria in coverage are met.