# Medical Policy

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| **Subject:** | Lung and Lobar Transplantation | | |
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## Description/Scope

This document addresses lung transplantation (lobar, single-lung or double-lung replacement). In a lobar transplantation, a lobe of the donor's lung is excised, sized appropriately for the recipient's thoracic dimensions, and is transplanted into the recipient. Donors for lobar lung transplantation have primarily been living related, but lobes of deceased donors have also been transplanted. In single-lung transplantation, only one lung from a deceased donor is provided to the recipient. In double-lung transplantation, the recipient's lungs are removed and replaced by both deceased donor's lungs.

**Note:** Please see the following related document for additional information:

- TRANS.00026 Heart/Lung Transplantation

## Position Statement

**Medically Necessary:**

Lung or lobar transplantation is considered **medically necessary** for individuals who meet the general individual selection criteria **and** have irreversible, progressively disabling, end-stage pulmonary disease including, but not limited to, one or more of the conditions listed below.

A. Restrictive lung disease, examples of which include, but are not limited to:
   1. Idiopathic pulmonary fibrosis (IPF);
   2. Interstitial pulmonary fibrosis;
   3. Scleroderma;
   4. Sarcoidosis;
   5. Extrinsic allergic alveolitis;
   6. Post-chemotherapy disease;
   7. Asbestosis.

B. Chronic lung disease, examples of which include, but are not limited to:
   1. Alpha-1 antitrypsin deficiency;
   2. Eosinophilic granuloma (Langerhans cell histiocytosis or histiocytosis X);
   3. Chronic Obstructive Pulmonary Disease (COPD) (emphysema, chronic bronchitis);
   4. Bronchiolitis obliterans;
   5. Bronchopulmonary dysplasia;
   6. Recurrent pulmonary embolus;
   7. Lymphangiomyomatosis (LAM).

C. Pulmonary hypertension, examples of which include, but are not limited to:

1. Primary pulmonary hypertension;
2. Pulmonary hypertension due to cardiac diseases and interstitial pulmonary fibrosis;
3. Eisenmenger's syndrome;
4. Fibrosing mediastinitis.

D. Septic lung disease, examples of which include, but are not limited to:
1. Cystic fibrosis;
2. Bronchiectasis.

**Lung or Lobar Retransplantation**

Retransplantation in individuals with graft failure of an initial lung or lobar transplant, due to either technical reasons or hyperacute rejection is considered **medically necessary.**

Retransplantation in individuals with chronic rejection or recurrent disease is considered **medically necessary** when the individual meets general selection criteria as defined below.

**Investigational and Not Medically Necessary:**

Lobar or lung transplantation in individuals for all other diagnoses is considered **investigational and not medically necessary.**

**Note:** For multi-organ transplant requests, criteria must be met for each organ requested. In those situations, an individual may present with a concurrent medical condition which would be considered an exclusion or a comorbidity that would preclude a successful outcome but would be treated with the other organ transplant. Such cases will be reviewed on an individual basis for coverage determination to assess the member's candidacy for transplantation.

**General Individual Selection Criteria**

In addition to having end stage pulmonary disease, the individual must not have a contraindication, as defined by the American Society of Transplantation in Guidelines for the Referral and Management of Patients Eligible for Solid Organ Transplantation (2001)* listed below.

**Absolute Contraindications- for Transplant *Recipients*** include, but are not limited to, the following:

A. Metastatic cancer;
B. Ongoing or recurring infections that are not effectively treated;
C. Serious cardiac or other ongoing insufficiencies that create an inability to tolerate transplant surgery;
D. Serious conditions that are unlikely to be improved by transplantation as life expectancy can be finitely measured;
E. Demonstrated individual nonadherence, which places the organ at risk by not adhering to medical recommendations;
F. Potential complications from immunosuppressive medications are unacceptable to the individual;

G. Acquired immune deficiency syndrome (AIDS) (diagnosis based on Centers for Disease Control and Prevention [CDC] definition of CD4 count, 200 cells/$mm^3$) unless the following are noted:
   1. CD4 count greater than 200 cells/$mm^3$ for greater than 6 months;
   2. HIV-1 RNA undetectable;
   3. On stable anti-retroviral therapy greater than 3 months;
   4. No other complications from AIDS (for example, opportunistic infection, including aspergillus, tuberculosis, coccidioidomycosis, resistant fungal infections, Kaposi's sarcoma or other neoplasm);
   5. Meeting all other criteria for lung transplantation.

* Steinman, Theodore, et al. Guidelines for the Referral and Management of Patients Eligible for Solid Organ Transplantation. Transplantation. 2001; 71(9):1189-1204.

**Rationale**

For individuals with end-stage lung disease not amenable to or refractory to available medical and surgical approaches, lung transplantation may be the only accepted therapeutic option available. Lung transplantation techniques and immunosuppressive therapies have evolved over time, with the bulk of experience accumulated since 1990. Refinement of surgical techniques, individual selection criteria, and postoperative management has resulted in improved outcomes for lung transplantation. Current published literature includes retrospective studies, guidelines and reviews which indicate that lung transplantation may improve overall survival (OS) in select individuals with a variety of end-stage lung diseases.

In 2006, the National Institute for Health Care and Excellence (NICE) published a document titled *Living-donor Lung Transplantation for End-Stage Lung Disease Guidance*, which states:

> Current evidence on the efficacy of living-donor lung transplantation for end-stage lung disease and its safety profile for suitable recipients appears adequate to support the use of this procedure. The procedure should only be used in selected patients who would otherwise die. However, limited evidence suggests that living-donor lung transplantation for end-stage lung disease carries a significant risk of morbidity for donors. Therefore, clinicians wishing to undertake this procedure should take the following actions: Ensure that donors receive thorough physical and psychological screening, and counselling about the morbidity associated with this procedure. They should also be provided with clear written information. Living-donor lung transplantation for end-stage lung disease should only be performed in specialist centers in the context of a multidisciplinary team. Donor lungs should be harvested by specialist thoracic surgeons.

NICE indications include the following:

- 2.11 Lung transplants are performed in patients with non-malignant pulmonary disease that is unresponsive or minimally responsive to treatment and who have a life expectancy of less than a year. The underlying causes include cystic fibrosis, severe pulmonary fibrosis, pulmonary hypertension and obliterative bronchiolitis.
- 2.12 The majority of live-donor lung recipients are patients with cystic fibrosis. The majority of lung donors are first-degree relatives who are compatible in terms of size and ABO blood group.

- 2.13 Living donation is an alternative to cadaveric organ donation. Living donation is an option for patients for whom cadaveric transplantation is unavailable, or who are deteriorating clinically to the point of transplant ineligibility while waiting for a cadaveric donor. Living donation may also be an option for critically ill children, as there is a particular shortage of suitable cadaveric donors for this age group.

Kreider and Kotloff (2009), in a report on the selection of lung transplantation candidates, stated that "Lung transplantation is a therapeutic option for a broad spectrum of chronic debilitating pulmonary disorders of the airways, parenchyma and vasculature." The authors also noted, "The selection of candidates requires an appreciation of the natural history of advanced lung disease as well as the impact of pretransplant patient characteristics on post-transplantation outcomes."

Orens (2009), in a review of the current status of lung transplantation, reported that, "Lung transplantation is an established treatment option for those with a wide variety of end-stage lung diseases and can prolong survival." In addition, the author noted that survival statistics for lung transplantation are not as favorable as for other solid organ transplants; lung transplants having a half-life of around 5 years versus 10 years for heart, kidney, and liver transplants. Yusen (2009) indicated that the literature provides conflicting data on survival and quality of life outcomes. This author encouraged development and reporting of valid measures of outcomes such as symptom control and function, as well as survival, which will assist individuals in weighing the potential costs and benefits of lung transplantation.

Todd and colleagues (2013), in a lung transplant update, reported that the number of potential candidates who could benefit from this procedure far exceeded the number of lung transplants performed annually, especially in the pediatric population. The authors also indicated that recently the epidemiology of those undergoing transplantation has changed considerably with a large increase in the proportion of older recipients and those with interstitial lung disease.

The Pulmonary Transplantation Council of the International Society for Heart and Lung Transplantation (ISHLT) issued a 2021 updated consensus document for the selection of lung transplant candidates. The authors (Leard and colleagues, 2021) include the following information:

**General Considerations**

Lung transplantation should be considered for adults with chronic, end-stage lung disease who meet all the following general criteria:

- High (>50%) risk of death from lung disease within 2 years if lung transplantation is not performed.

- High (>80%) likelihood of 5-year post-transplant survival from a general medical perspective provided that there is adequate graft function.

**Pediatric Candidate Selection**

***Timing of Listing***

In addition to general recommendations for adults, considerations for listing children for lung transplant include the following:

- Patients with CF < 18 years of age should be listed when $FEV_1$ < 30% predicated
- Patients with PAH < 18 years of age should be listed when they are in the EPPVDN high risk category and on optimal therapy without improvement

Transition from pediatric to adult care while on the transplant waiting list needs careful planning, timing, and ongoing communication

In pediatric candidates, growth and nutritional status should be carefully monitored.

Extracorporeal life support may be an acceptable bridge to transplant in appropriately selected pediatric candidates at centers with expertise.

Valapour and colleagues, (2021) reported in the Organ Procurement Transplant Network (OPTN)/ Scientific Registry of Transplant Recipients that lung transplants declined in 2020, this coincided with the COVID-19 pandemic. In 2022, they reported that for the first time since the pandemic, the annual number of lung transplants performed in the United States increased. There were 2743 lung transplants performed representing an increase of 174 lung transplants from 2569 in 2021. The number did not reach pre-pandemic volumes. The number of new adult candidates added to the waiting list continued to increase annually, with 3161 candidates added in 2022.

The Pulmonary Transplantation Council of the ISHLT committee consensus update (2021) addressed use of lung transplantation in individuals with acute respiratory distress syndrome (ARDS) and COVID-19. The committee concluded:

> Case reports describing bilateral lung transplant for COVID-19 associated ARDS have started to emerge since January 2020. Experts in the field recommend waiting at least 4-6 weeks after the onset of respiratory failure due to COVID-19 prior to considering lung transplant. While it seems likely that these cases should be evaluated like other patients with post-viral ARDS, it is too early to make conclusive recommendations at this time.

Mi and colleagues (2024) performed a meta-analysis that summarized the clinical experience of individuals with COVID-19 ARDS versus pulmonary fibrosis that received lung transplantation and compared the outcomes. Eight studies included 478 COVID lung transplant recipients and 163 non-COVID-19 lung transplants. The pooled hospital mortality and follow up survival rates was 0.00% and 87.4%, respectively. Compared to non-COVID-19 lung transplant recipients, the COVID-19 lung transplant recipients were associated with higher rates of primary graft dysfunction (PGD) ($p<0.001$).

*Lobar Transplantation*

Several authors (Date, 2012; Inci, 2012) indicate that living donor lobar lung transplantation (LDLLT) is a reasonable treatment option for carefully selected individuals with end-stage lung disease who are unlikely to

survive or who may deteriorate clinically to the point of transplant ineligibility during the wait for a compatible deceased donor, but who are otherwise eligible candidates for unilateral or bilateral lung transplantation. LDLLT provides health benefits by improving respiratory and cardiac function and quality of life and by prolonging survival in those who otherwise are likely to die. While a number of recipients experience complications or die, the likelihood of survival without transplant is extremely low. There is some evidence that LDLLT may be more efficacious than deceased donor lung transplant for certain individuals, for example, it leads to greater improvement in respiratory function, and that the incidence of chronic rejection is lower than that for cadaveric transplantation. In a retrospective review, Toyooka and colleagues (2009) analyzed the outcome of bronchial healing after LDLLT and reported that bronchial healing after this procedure was acceptable.

Donors for lobar transplantation have been primarily living-related donors, with one lobe obtained from each of two donors (generally mother and father) to a child when bilateral lung transplantation is required. Based upon evidence from several studies (Barr, 2005; Bowdish, 2005), lobar lung transplantation may also be beneficial in adults with primary pulmonary hypertension, idiopathic pulmonary fibrosis, cystic fibrosis, or those who require retransplantation. Bowdish and colleagues (2005) reported that when compared with bilateral cadaveric lung transplantation, LDLLT provided comparable intermediate and long term pulmonary function and exercise capacity.

A 2015 retrospective review by Date and colleagues reported that LDLLT provides similar survival to cadaveric lung transplantation. The authors compared the preoperative status and outcome of LDLLT recipients with those of cadaveric lung transplantation (CLT) recipients. A total of 79 lung transplants (42 LDLLTs and 37 CLTs) were performed at a single Japanese center between June 2008 and January 2014. Prior to transplantation, LDLLT recipients were reported to be more debilitated than CLT recipients due to a lower body mass index, less ability to ambulate and greater ventilator dependence. Postoperatively, LDLLT recipients required longer mechanical ventilation. Survival rates at 1 and 3 years were similar between the LDLLT and CLT groups (89.7% and 86.1% vs 88.3% and 83.1%, p=0.55). Additionally, all living donors returned to their previous activities without restriction. The authors concluded that LDLLT is a viable option for those too ill to survive a long waiting period for cadaveric donors.

In 2018, Roy and colleagues reported findings from a retrospective, single-center analysis of 419 participants who underwent lung transplantation. Of those, 29 participants (6.9%) were retransplantations due to chronic lung allograft dysfunction (CLAD). Time from primary lung transplant to retransplantation ranged from 304 days to 3971 days (median time = 1163 days). The authors concluded that lung retransplantation was a viable treatment option for appropriately selected individuals with CLAD after primary lung transplant. “Lung retransplant recipients with CLAD are younger with higher LAS and challenging preoperative management, but they have outcomes comparable with those of primary lung transplant recipients.”

Di and colleagues (2024) published a meta-analysis of 10 cohort studies which compared the prognosis of lung transplant recipients based on age. Prognosis of recipients was investigated based on donor age, the primary outcomes measured were 1-year OS, 3-year OS, 5-year OS, and 5-year CLAD-free survival. Inclusion criteria were recipients who met the criteria for lung transplant and had a successful transplant; recipients used an elderly donor; recipients that used a younger donor; OS, the occurrence of primary graft dysfunction (PGD) II or III, the occurrence of CLAD, and hospital length of stay. Results demonstrated that the older donor group showed no

significant difference from the young donor group in PGD within 72 hours, use of extracorporeal membrane oxygenation, length of ventilator use, and intensive care unit hours. However, a longer hospital stay was associated with the older donor group. There was no difference found in long-term outcomes between the two groups in 1-year OS (p=0.96), 3-year OS (p=0.30), and 5-year OS (p=0.37). Four studies provided 5-year CLAD-free survival, and the pooled results showed a higher 5-year CLAD-free survival in the older donor group compared to the younger donor group (p=0.03). The authors concluded that older donors are not inferior to younger donors in terms of recipient outcomes and that lung transplant using older donors is a potential therapeutic option.

*Pediatric Lung Transplantation*

Benden colleagues (2012) reviewed pediatric lung transplantations (recipients aged 18 and younger) reported to the ISHLT Registry. The authors noted that an increased number of pediatric lung transplants had occurred in recent years. There were 73 pediatric lung transplants in 2000 as compared to 126 transplants in 2010. The most common indication for pediatric lung transplant was cystic fibrosis (CF), accounting for 54% of lung transplants in 6-11 year-olds and 72% of lung transplants in 12-17 year-olds that occurred between 1990 and June 2011. Survival at 5 years was not significantly different from adult recipients. The half-life, estimated time at which 50% of recipients have died, was 4.7 years for children and 5.3 years for adults. For children receiving allografts between 2002 and June 2010, the 5-year survival rate was 54% and 7-year survival was 44%. Children aged 1 to 11 years had a significantly better survival rate than those between the ages of 12 and 17 years (half-life of 6.2 years and 4.3 years, respectively). In the first year after lung transplantation, non-cytomegalovirus infection and graft failure were the leading causes of death. Bronchiolitis obliterans syndrome was the major cause of death beyond 3 years after transplantation.

The CF Foundation lung transplant referral guidelines recommend annual conversations with people with CF once their forced expiratory volume in one second (FEV1) is <50% predicted. Considering lung transplant as a treatment option before it is medically needed will allow more time to address any barriers to lung transplant that may exist. A clinical trial (NCT06030206) with a projected completion date of July 2027, main objective is to test whether a research website improves individual preparedness for discussions about lung transplant, and to understand whether there are unique factors that affect people with CF from communities with decreased access to transplant ("communities of concern").

*Lung Allocation Score*

The United Network for Organ Sharing (UNOS) Lung Allocation Score (LAS) is a numerical score used to prioritize awaiting candidates 12 years of age or older for lung transplant in the United States. This system is intended to ensure fair and equitable allocation of organs based on urgency rather than waiting time. A higher score signals a more urgent need for transplant. Specific factors in the scoring system include the severity of the candidate's illness, the ability to cope with transplant surgery, and predicted lifespan after the transplant. Waitlist urgency is defined as what is expected to happen to a candidate, given their characteristics, in the next year if a transplant is not received. Post-transplant survival is defined as what is expected to happen to a candidate, given their characteristics, in the first year after a transplant, if a transplant is not received (UNOS, 2020).

McCue and colleagues (2007) studied the impact of the LAS on early complications, 90-day survival, and incidence of PGD post-transplant. A total of 78 recipients receiving transplants after the initiation of the LAS were compared with 78 recipients transplanted prior to the start of the new system. The authors reported that the LAS system did not result in greater mortality, major complications or increased incidence of severe PGD.

Kozower and colleagues (2008) performed a retrospective cohort study using data from five academic medical centers to evaluate the impact of LAS on short-term outcomes after lung transplantation. This score changed lung allocation from a system based on waiting time to an algorithm based on the probability of survival for 1 year on the transplant list and survival 1 year post-transplantation. Results were compared for 170 lung transplant recipients on the basis of the new lung allocation scores (May 4, 2005 to May 3, 2006) with those obtained from 171 lung transplant recipients who underwent transplants the preceding year before implementation of the scoring system. Waiting time decreased from 681 to 445.6 days ($p<0.001$). Recipient diagnoses changed with an increase (15% to 25%) in idiopathic pulmonary fibrosis cases and decreases in emphysema (46% to 34%) and cystic fibrosis (23% to 13%). Hospital mortality and 1-year survival were the same between groups (5.3% vs. 5.3% and 90% vs. 89%, respectively). Presumably due to increased severity of illness, the incidence of PGD and postoperative intensive care unit length of stay increased in the year after implementation of the scoring system; graft dysfunction grew from 14.8% (24/170) to 22.9% (39/171) ($p=0.04$); and length of stay rose from 5.7 to 7.8 days.

Prior to LAS implementation, data indicated that survival was better in double-lung than single-lung transplant recipients (median survival, 6.7 vs 4.6 years; $p<0.001$). However, this association was confounded by large differences between the recipient populations, particularly due an individual's underlying condition. Schaffer and colleagues (2015) retrospectively assessed and compared recipient outcomes of single and double lung transplants performed since the LAS was implemented in 2005. An exploratory analysis was performed on adults with idiopathic pulmonary fibrosis (IPF) or chronic obstructive pulmonary disease (COPD) and documented LAS who underwent lung transplantation in the United States between May 4, 2005 and December 31, 2012. Participants were identified in the UNOS thoracic registry. Individuals with IPF (n=4134, of whom 2010 received a single-lung and 2124 received double-lung transplantation) or COPD (n=3174, of whom 1299 received a single-lung and 1875 received double-lung transplantation) were identified as having undergone lung transplantation since May 2005. Median follow-up was 23.5 months. Of the participants with IPF, 1380 (33.4%) died and 115 (2.8%) underwent retransplantation. Of those with COPD, 1138 (34.0%) died and 59 (1.9%) underwent retransplantation. The interaction between diagnosis type (COPD or IPF) and graft failure was substantial ($p=0.049$). Double-lung transplants were associated with better graft survival in IPF recipients but not in those with COPD. The authors concluded that since the implementation of a medical need-based lung allocation system, double lung transplantation was associated with better survival than single-lung transplantation in those with IPF. In individuals with COPD, there was no survival difference noted between single and double lung transplantation at 5 years.

In 2021, the OPTN Lung Transplant Committee updated how lung transplants are allocated in the United States. Since 2005, potential lung transplant recipients have been ranked according to the Lung Allocation score (LAS). UNOS made changes to the updated cohort for calculation of the LAS approved by the OPTN Board of Directors, the update improves the predication of candidates' expected survival on the waitlist and post-transplant to improve equity in lung allocation.

In 2023, the OPTN published a new policy for matching lung transplant candidates with organs from deceased donors. The new "continuous distribution" methodology states that all of the factors in the organ match are included in a single, weighted score, calculated for each lung transplant candidate, and each potential lung from a donor.

Statistical modeling suggests this will reduce the number of lung candidates who die awaiting a lung transplant, but it will increase transplant access for a number of candidates. This includes candidates who are:

- The most medically urgent
- Younger than age 18
- A prior living organ donor
- More likely to have immune system rejection of many organs
- Short in stature
- Expected to live longer after a transplant

All lung transplant candidates aged 12 and older will receive a lung Composite Allocation Score (lung CAS) that replaces the LAS. For candidates younger than age 12, the two existing priority rankings will still be utilized. With the CAS, candidates receive varying numbers of points based on a set of different attributes. The attributes are weighted. The categories of attributes include the following:

- Candidate medical urgency (maximum 25 points)
- Likelihood of recipient survival over five years post-transplant (maximum 25 points)
- Potential biological challenges in matching, such as the candidate's blood type, height or immune sensitivity (maximum 15 points)
- Whether the candidate was younger than age 18 when listed for a transplant (20 points)
- Whether the candidate was a prior living organ donor (five points)
- A final category of attributes, worth as many as 10 points, is determined by each lung offer from a donor who is a potential match for the candidate. More points will be assigned to matches where the donor hospital and the candidates' transplant hospital are closer to one another, and where the logistics of preserving and transporting the lungs between the two hospitals are more likely to result in a successful transplant. Because this portion of the lung CAS may be different for every organ offer, the total score will not remain the same for all patients and all matches.

## Background/Overview

Lung transplantation refers to a lobar, single-lung or double-lung replacement. In a lobar transplant, a lobe of the donor's lung is excised, sized appropriately for the recipient's thoracic dimensions and is transplanted. Donors for lobar transplantation have primarily been living related, but there are also cases of deceased donor lobar transplants. In a single-lung transplant, only one lung is removed from the recipient and replaced with a deceased donor lung. In a double-lung transplant, both lungs of the recipient are removed and replaced by the deceased donor's lungs.

The most common indication for lung transplantation in adults is chronic obstructive pulmonary disease (COPD). COPD is a progressive lung disease that makes it more difficult to breathe over time. It is a leading cause of death and illness worldwide. Most COPD is caused by long-term cigarette smoking but other lung irritants such as air pollution may also be contributing factors. Other primary diagnoses for those receiving lung transplants include CF, idiopathic pulmonary fibrosis (IPF), primary pulmonary hypertension (PPH), and retransplantation after graft failure. CF is a genetic disorder that affects the respiratory, digestive and reproductive systems. IPF is scarring or thickening of the lungs without a known cause. It is a debilitating disorder with no proven treatment and a median survival from the time of diagnosis in the range of 3 to 4 years (Kreider, 2009). PPH is also currently termed idiopathic pulmonary arterial hypertension (IPAH). PPH or IPAH is a rare lung disorder in which the blood pressure in the pulmonary artery rises far above normal levels, usually with no apparent reason. Secondary pulmonary hypertension (SPH) means the cause is known. Common causes of SPH are the breathing disorders emphysema and bronchitis.

The limiting factor for lung transplantation is the short supply of donor organs. The procurement and distribution of lung organs for transplantation in the United States is under the direction of the UNOS. A national database of transplant candidates, donors, recipients, and donor-recipient matching and histocompatibility is maintained by UNOS. According to UNOS, the LAS can be used to estimate each transplant candidate's severity of illness and expected post-transplant survival. Clinical information including a candidate's diagnosis and test results are used to calculate an LAS that ranges from 0-100. A lung transplant candidate with a higher LAS will receive higher priority for a compatible lung offer in the same geographic zone. Modifications to the LAS system were last implemented in September 2021 (UNOS, 2022). The updated LAS calculation is data from a more recent cohort of lung candidates and recipients. Several variables have been removed from the waiting list urgency measure and the post-transplant survival measure.

In 2021 the American Society of Transplant Surgeons (ASTS) Statement Concerning Eligibility for Solid Organ Transplant Candidacy noted:

> The ASTS advocates transplanting as many of these patients, as quickly as possible, while also making the most responsible use of our nation's organ supply. Limiting a transplanted organ's life expectancy due to placing it with a patient, or in a situation, in which it cannot be adequately supported can deprive another waitlisted patient of a better outcome with the same organ.
>
> To this end, we feel that any medically eligible patient, with sufficient support in place to allow for their adequate care following surgery, should be supported in their pursuit of transplantation.
>
> When a patient presents to a transplant center for evaluation, the center makes a judgement concerning the patient's medical fitness to undergo the procedure, and also the patient's expected ability to capably care for themselves and a new organ.
>
> If the patient has cognitive, physical, or financial limitations that would preclude them from being able to adequately care for themselves, then appropriate social supports or other compensatory mechanisms which would remediate the situation should be identified. If these can be found, then the patient's candidacy for transplantation should be supported. If, however, they cannot be identified, proceeding with transplantation could threaten both the patient's health and safety, and

the longevity of a donated organ. In such a case, further evaluation should be deferred until the limiting issue can be corrected.

As such it is the recommendation of the ASTS that no patient will be discriminated against or precluded from transplant listing solely due to the presence of a disability or handicap whether physical or psychological. However, if these disabilities lead to a clinical reality where the patient will suffer a great risk of morbidity or mortality from the transplant surgery itself, or the subsequent placement on lifelong immunosuppression, then transplantation would not be recommended. This decision would be made due to the clinical risk benefit analysis for the specific patient, and not on any external factors.

## Coding

*The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.*

**When services may be Medically Necessary when criteria are met:**

| | |
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| **CPT** | |
| 32850 | Donor pneumonectomy(s) (including cold preservation), from cadaver donor |
| 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 |
| 32855 | Backbench standard preparation of cadaver donor lung allograft prior to transplantation, including dissection of allograft from surrounding soft tissues to prepare pulmonary venous/atrial cuff, pulmonary artery, and bronchus; unilateral |
| 32856 | Backbench standard preparation of cadaver donor lung allograft prior to transplantation, including dissection of allograft from surrounding soft tissues to prepare pulmonary venous/atrial cuff, pulmonary artery, and bronchus; bilateral |
| **HCPCS** | |
| S2060 | Lobar lung transplantation |
| S2061 | Donor lobectomy (lung) for transplantation, living donor |
| **ICD-10 Procedure** | |
| 0BYC0Z0-0BYC0Z1 | Transplantation of right upper lung lobe, open approach [allogeneic, syngeneic] |
| 0BYD0Z0-0BYD0Z1 | Transplantation of right middle lung lobe, open approach [allogeneic, syngeneic] |
| 0BYF0Z0-0BYF0Z1 | Transplantation of right lower lung lobe, open approach [allogeneic, syngeneic] |

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|---|---|
| 0BYG0Z0-0BYG0Z1 | Transplantation of left upper lung lobe, open approach [allogeneic, syngeneic] |
| 0BYH0Z0-0BYH0Z1 | Transplantation of lung lingula, open approach [allogeneic, syngeneic] |
| 0BYJ0Z0-0BYJ0Z1 | Transplantation of left lower lung lobe, open approach [allogeneic, syngeneic] |
| 0BYK0Z0-0BYK0Z1 | Transplantation of right lung, open approach [allogeneic, syngeneic] |
| 0BYL0Z0-0BYL0Z1 | Transplantation of left lung, open approach [allogeneic, syngeneic] |
| 0BYM0Z0-0BYM0Z1 | Transplantation of bilateral lungs, open approach [allogeneic, syngeneic] |

**ICD-10 Diagnosis**

All diagnoses

**When services are Investigational and Not Medically Necessary:**
For the procedure codes listed above when criteria are not met; or when the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

## References

**Peer Reviewed Publications:**

1. Barr ML, Schenkel FA, Bowdish ME, Starnes VA. Living donor lobar lung transplantation: current status and future directions. Transplant Proc. 2005; 37(9):3983-3986.
2. Benden C, Edwards LB, Kucheryavaya AY, et al. International Society of Heart and Lung Transplantation. The Registry of the International Society for Heart and Lung Transplantation: fifteenth pediatric lung and heart-lung transplantation report--2012. J Heart Lung Transplant. 2012; 31(10):1087-1095.
3. Bowdish ME, Pessotto R, Barbers RG, et al. Long-term pulmonary function after living-donor lobar lung transplantation in adults. Ann Thorac Surg. 2005; 79(2):418-425.
4. Date H, Aoe M, Sano Y, et al. Improved survival after living-donor lobar lung transplantation. J Thorac Cardiovasc Surg. 2004; 128(6):933-940.
5. Date H, Sato M, Aoyama A, et al. Living-donor lobar lung transplantation provides similar survival to cadaveric lung transplantation even for very ill patients†. Eur J Cardiothorac Surg. 2015; 47(6):967-972; discussion 972-973.
6. Date H, Shiraishi T, Sugimoto S, et al. Outcome of living-donor lobar lung transplantation using a single donor. J Thorac Cardiovasc Surg. 2012; 144(3):710-715.
7. Date H, Yamane M, Toyooka S, et al. Current status and potential of living-donor lobar lung transplantation. Front Biosci. 2008; 13:1433-1439.
8. Di Y, Fu R, Xiang Z, et al. Comparison of prognosis for lung transplantation between older and younger donors: A systematic review and meta-analysis based on cohort studies. Ann Thorac Cardiovasc Surg. 2024; 30(1):24-00092.
9. Dauriat G, Mal H, Thabut G, et al. Lung transplantation for pulmonary Langerhans' cell histiocytosis: a multicenter analysis. Transplantation. 2006 81(5):746-750.
10. Egan TM, Edwards LB. Effect of the lung allocation score on lung transplantation in the United States. J Heart and Lung Transplant. 2016; 35(4):433-439.
11. Goldberg HJ, Deykin A. Advances in lung transplantation for patients who have cystic fibrosis. Clin Chest Med. 2007; (2):445-457.

12. Inci I, Schuurmans MM, Kestenholz P, et al. Long-term outcomes of bilateral lobar lung transplantation. Eur J Cardiothorac Surg. 2013; 43(6):1220-1225.
13. Kozower BD, Meyers BF, Smith MA, et al. The impact of the lung allocation score on short-term transplantation outcomes: a multicenter study. J Thorac Cardiovasc Surg. 2008; 135(1):166-171.
14. Kpodonu J, Massad MG, Chaer RA, et al. The US experience with lung transplantation for pulmonary lymphangioleiomyomatosis. J Heart Lung Transplant. 2005; 24(9):1247-1253.
15. Kreider M, Kotloff RM. Selection of candidates for lung transplantation. Proc Am Thorac Soc. 2009; 6(1):20-27.
16. Liou TG, Woo MS, Cahill BC. Lung transplantation for cystic fibrosis. Curr Opin Pulm Med. 2006; (6):459-463.
17. Massad MG, Powell CR, Kpodonu J. Outcomes of lung transplantation in patients with scleroderma. World J Surg. 2005; 29(11):1510-1515.
18. Maurer JR. Patient selection criteria for lung transplantation. JAMA. 2001; 286(21):2720-2721.
19. McCue JD, Mooney J, Quail J, et al. Ninety-day mortality and major complications are not affected by use of lung allocation score. J Heart Lung Transplant. 2008; 27(2):192-196.
20. Mi X, Zhang X, Dai Z, et al. Clinical characteristics and outcomes of lung transplantation in patients with severe COVID-19 infection: A systematic review and meta-analysis. Int J Infect Dis. 2024; 147:107176.
21. Nathan, SD. Lung transplantation- disease specific considerations for referral. Chest. 2005; 127(3):1006-1016.
22. Nauser TD, Stites SW. Diagnosis and treatment of pulmonary hypertension. Am Fam Physician. 2001; 63(9):1789-1798.
23. Orens JB, Garrity ER Jr. General overview of lung transplantation and review of organ allocation. Proc Am Thorac Soc. 2009; 6(1):13-19.
24. Roy SB, Panchanathan R, Walia R, et al. Lung retransplantation for chronic rejection: A single-center experience. Ann Thorac Surg. 2018; 105(1):221-227.
25. Ruttmann E, Geltner C, Bucher B, et al. Combined CMV prophylaxis improves outcome and reduces the risk for bronchiolitis obliterans syndrome (BOS) after lung transplantation. Transplantation. 2006; 81(10):1415-1420.
26. Schaffer JM, Singh SK, Reitz BA, Zamanian RT, Mallidi HR. Single- vs double-lung transplantation in patients with chronic obstructive pulmonary disease and idiopathic pulmonary fibrosis since the implementation of lung allocation based on medical need. JAMA. 2015; 313(9):936-948.
27. Singer LG, Gould MK, Tomlinson G, Theodore J. Determinants of health utility in lung and heart-lung transplant recipients. Am J Transplant. 2005; 5(1):103-109.
28. Smeritschnig B, Jaksch P, Kocher A, et al. Quality of life after lung transplantation: a cross-sectional study. J Heart Lung Transplant. 2005; 24(4):474-480.
29. Todd JL, Christie JD, Palmer SM. Update in lung transplantation 2013. Am J Respir Crit Care Med. 2014; 190(1):19-24.
30. Toyooka S, Yamane M, Oto T, et al. Bronchial healing after living-donor lobar lung transplantation. Surg Today. 2009; 39(11):938-943.
31. Trulock EP, Edwards LB, Taylor DO, et al. The Registry of the International Society for Heart and Lung Transplantation: twenty-first official adult lung and heart-lung transplant report – 2004. J Heart Lung Transplant. 2004; 23(7):804-815.
32. Vizza CD, Yusen RD, Lynch JP, et al. Outcome of patients with cystic fibrosis awaiting lung transplantation. Am J Respir Care Med. 2000; 162(3 Pt 1):819-825.

33. Yusen RD. Technology and outcomes assessment in lung transplantation. Proc Am Thorac Soc. 2009; 6(1):128-136.

**Government Agency, Medical Society, and Other Authoritative Publications:**

1. Abecassis M, Adams M, Adams P, et al.; Live Organ Donor Consensus Group. Consensus statement on the live organ donor. JAMA. 2000; 284(22):2919-2926.
2. American Society of Transplant Surgeons. ASTS Statement Concerning Eligibility for Solid Organ Transplant Candidacy. Available at: https://www.asts.org/docs/default-source/position-statements/asts-statement-concerning-eligibility-for-solid-organ-transplant-candidacy.pdf?sfvrsn=1a6b4ed3_3. Accessed on August 22, 2024.
3. Leard LE, Holm AM, Valapour M, et al. Consensus statement. Consensus document for the selection of lung transplant candidates: an update from the International Society for Heart and Lung Transplantation. J Heart Jung Transplant. 2021; 40(11):1349-1379.
4. National Institute for Health Care and Excellence (NICE) Guidance Living-donor lung transplantation for end-stage lung disease. May 24, 2006. Available at: livingdonor-lung-transplantation-for-endstage-lung-disease-pdf-1899863394343621 (nice.org.uk). Accessed on August 22, 2024.
5. Organ Procurement and Transplantation Network (OPTN) and Scientific Registry of Transplant Recipients (SRTR). OPTN/SRTR 2021 Annual Data Report. U.S. Department of Health and Human Services, Health Resources and Services Administration; 2023. Available at: http://srtr.transplant.hrsa.gov/annual_reports/Default.aspx. Accessed August 20, 2024.
6. Organ Procurement and Transplantation Network (OPTN) and Scientific Registry of Transplant Recipients (SRTR). OPTN/SRTR 2022 Annual Data Report. U.S. Department of Health and Human Services, Health Resources and Services Administration; 2024. Available at: Lung (hrsa.gov). Accessed on August 22, 2024.
7. Steinman TI, Becker BN, Frost AE, et al.; Clinical Practice Committee, American Society of Transplantation. Guidelines for the referral and management of patients eligible for solid organ transplantation. Transplantation. 2001; 71(9):1189-1204.
8. United Network for Organ Sharing. Policy 10: Allocation of Lungs. Effective July 25, 2024. Available at: https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf. Accessed on August 20, 2024.
9. United Network for Organ Sharing. Lung Continuous Distribution Policy. Effective March 9, 2023. Available at: https://optn.transplant.hrsa.gov/professionals/by-organ/heart-lung/lung-continuous-distribution-policy/. Accessed on August 20, 2024.
10. Verleden GM, Glanville AR, Lease ED, et al. Chronic lung allograft dysfunction: Definition, diagnostic criteria, and approaches to treatment – A consensus report from the Pulmonary Council of the ISHLT. J Heart Lung Transplant. 2019; 38(5):493-503.
11. Weill D, Benden C, Corris PA, et al. A consensus document for the selection of lung transplant candidates: 2014--an update from the Pulmonary Transplantation Council of the International Society for Heart and Lung Transplantation. J Heart Lung Transplant. 2015; 34(1):1-15.

## Websites for Additional Information

1. American Lung Association. Available at: https://www.lung.org/. Accessed on August 20, 2024.
2. American Thoracic Society (ATS). Available at: http://www.thoracic.org. Accessed on August 20, 2024.

3. Cystic Fibrosis Foundation (CFF) Lung Transplant Referral Guidelines. Available at: https://www.cff.org/medical-professionals/lung-transplant-referral-guidelines#lung-transplant-referral-for-individuals-with-cystic-fibrosis-executive-summary. Accessed on August 20, 2024.
4. United Network for Organ Sharing (UNOS). A guide to calculation the lung allocation score. July 14, 2020. Available at: lung-allocation-score.pdf (unos.org). Accessed on August 22, 2024.
5. Primary Pulmonary Hypertension Association. Available at: http://www.phassociation.org/. Accessed on August 20, 2024.
6. Pulmonary Fibrosis Foundation. Available at: http://www.pulmonaryfibrosis.org/. Accessed on August 20, 2024.
7. Scientific Registry of Transplant Recipients. Available at: http://www.srtr.org/. Accessed on August 20 , 2024.
8. The International Society for Heart & Lung Transplantation. Available at: http://www.ishlt.org. Accessed on August 20, 2024.
9. for Organ Sharing. Available at: http://www.unos.org/. Accessed on August 20, 2024.

## Index



## Document History

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|---|---|---|
| Revised | 11/14/2024 | Medical Policy & Technology Assessment Committee (MPTAC) review. Reformatted INV and NMN statement. Revised “patients” to “individuals” and “noncompliance” to “nonadherence” in Absolute Contraindications for Transplant Recipients. Revised Rationale, References, and Websites sections. |
| Reviewed | 11/09/2023 | MPTAC review. Updated Rationale, References, and Website sections. |
| | 09/27/2023 | Updated Coding section to remove CPT codes 0494T, 0495T, 0496T now addressed in TRANS.00039. |
| Reviewed | 11/10/2022 | MPTAC review. Updated Rationale, Background, References and Websites sections. |
| Reviewed | 11/11/2021 | MPTAC review. Updated Rationale, Background, References and Websites sections. |

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| Reviewed | 03/22/2018 | MPTAC review. Updated References and Websites sections. |
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| | 12/27/2018 | The document header wording updated from "Current Effective Date" to "Publish Date." Updated Coding section with 01/01/2018 CPT changes; added 0494T, 0495T, 0496T. |
| Reviewed | 02/02/2017 | MPTAC review. Updated formatting in position statement section. Updated References and Websites sections. |
| Reviewed | 02/04/2016 | MPTAC review. Rationale, Background and Reference sections updated. Removed ICD-9 codes from Coding section. |
| Reviewed | 02/05/2015 | MPTAC review. Description, Rationale, Background and Reference sections updated. |
| Reviewed | 02/13/2014 | MPTAC review. Rationale, Background and Reference sections updated. |
| Reviewed | 02/14/2013 | MPTAC review. Rationale and Reference sections updated. |
| Revised | 02/16/2012 | MPTAC review. Updated listing of examples of conditions in position statement. Reference and Index sections updated. |
| Reviewed | 02/17/2011 | MPTAC review. Rationale, Background, References, and Index updated. |
| Reviewed | 02/25/2010 | MPTAC review. References links updated. |
| Revised | 02/26/2009 | MPTAC review. Position statement clarified by replacing the wording "obstructive lung disease" with "chronic lung disease". Rationale, background and references updated. |
| Reviewed | 02/21/2008 | MPTAC review. Updated description, rationale, background and references. Clarified note for multi-organ requests. The phrase "investigational/not medically necessary" was clarified to read "investigational and not medically necessary." This change was approved at the November 29, 2007 MPTAC meeting. |
| Revised | 03/08/2007 | MPTAC review. Clarification of diagnoses added to medical necessity criteria. Updated references and coding. |
| Reviewed | 03/23/2006 | MPTAC review. No changes to policy stance. References were updated with updated UNOS information about organ allocation process. . |
| Revised | 04/28/2005 | MPTAC review. Revision based on Pre-merger Anthem and Pre-merger WellPoint Harmonization. |

| **Pre-Merger Organizations** | **Last Review Date** | **Document Number** | **Title** |
|---|---|---|---|
| Anthem, Inc. | 09/19/2003 | TRANS.00009 | Lung and Lobar Transplantation |
| WellPoint Health Networks, Inc. | 12/02/2004 | 7.05.01 | Lung and Lobar Transplantation |