Healthy Blue

Medical Policy

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 patient noncompliance, which places the organ at risk by not adhering to medical recommendations;
F. Potential complications from immunosuppressive medications are unacceptable to the patient;

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. Vol. 71, 1189-1204, No. 9, May 15, 2001.

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. Although there are no randomized controlled trials available demonstrating the safety and efficacy of the procedure, current published literature does include retrospective studies, guidelines and reviews which indicate that lung transplantation may improve overall survival in select individuals with a variety of end-stage lung diseases.

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 issued a 2014 updated consensus document for the selection of lung transplant candidates. The authors (Weill and colleagues, 2015) include the following information:

> **General Candidacy 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 surviving at least 90 days after lung transplantation.
> - 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 referral (similarities with adult candidates):
>
> - A progressive lung disease on maximal medical therapy.
> - A short predicted life expectancy.
> - A poor quality of life.
> - Because the waiting times, particularly for smaller children, are longer, potential candidates should be referred to a transplant center as early as possible.
> - Appropriate child and family support in place. It is essential that the child, in particular, commits to the transplant procedure and close long-term follow-up.

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 (LTx). "Lung retransplant recipients with CLAD are younger with higher LAS and challenging preoperative management, but they have outcomes comparable with those of primary LTx recipients."

Pediatric Lung Transplantation

Benden and colleagues (2012) reviewed pediatric lung transplantations (recipients age 18 and younger) reported to the International Society for Heart and Lung Transplantation 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.

Lung Allocation Score

Prior to 2005, lung transplants were allocated in the United States according to time accumulated on the lung transplant wait list after matching blood type. Since 2005, potential lung transplant recipients have been ranked according to the Lung Allocation Score (LAS).

McCue and colleagues (2007) studied the impact of the LAS on early complications, 90-day survival, and incidence of primary graft dysfunction (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. The LAS was implemented in May 2005 by the Organ Procurement and Transplantation Network (OPTN). This new 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 primary graft dysfunction 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. Subjects were identified in the United Network for Organ Sharing 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 subjects 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.

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 United Network for Organ Sharing (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 a 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 November 2017. The new LAS calculation is mostly comprised of variables already reported by transplant programs.

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:

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
0494T	Surgical preparation and cannulation of marginal (extended) cadaver donor lung(s) to ex vivo organ perfusion system, including decannulation, separation from the perfusion system, and cold preservation of the allograft prior to implantation, when performed
0495T	Initiation and monitoring marginal (extended) cadaver donor lung(s) organ perfusion system by physician or qualified health care professional, including physiological and laboratory assessment (eg, pulmonary artery flow, pulmonary artery pressure, left atrial pressure, pulmonary vascular resistance, mean/peak and plateau airway pressure, dynamic compliance and perfusate gas analysis), including bronchoscopy and X ray when performed; first two hours in sterile field
0496T	Initiation and monitoring marginal (extended) cadaver donor lung(s) organ perfusion system by physician or qualified health care professional, including physiological and laboratory assessment (eg, pulmonary artery flow, pulmonary artery pressure, left atrial pressure, pulmonary vascular resistance, mean/peak and plateau airway pressure, dynamic compliance and perfusate gas analysis), including bronchoscopy and X ray when performed; each additional hour
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]
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.

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Websites for Additional Information

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Idiopathic Pulmonary Fibrosis (IPF)
Lobar Transplant
Lung Transplant
Primary Pulmonary Hypertension (PPH)
Pulmonary Fibrosis
Pulmonary Hypertension
Restrictive Lung Disease
Septic Lung Disease

Document History

Status	Date	Action
Reviewed	11/05/2020	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Rationale, Background, References and Websites sections.
Reviewed	11/07/2019	MPTAC review. Updated References and Websites sections.
Reviewed	01/24/2019	MPTAC review. Updated References and Websites sections.
Reviewed	03/22/2018	MPTAC review. Updated References and Websites sections.
Reviewed	02/27/2018	MPTAC review. Updated References and Websites sections.
	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