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Medical Policy Manual

Topic: Lung and Lobar Lung Transplant

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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

A lung transplant consists of replacing all or part of diseased lungs with healthy lung(s). Transplantation is an option for patients with end-stage lung disease.

Background

End-stage lung disease may be the consequence of a number of different etiologies. The most common indications for lung transplantation are chronic obstructive pulmonary disease (COPD), idiopathic pulmonary fibrosis, cystic fibrosis, alpha-1 antitrypsin deficiency, and idiopathic pulmonary arterial hypertension. Prior to the 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 end-stage lung disease despite these measures.

A lung transplant refers to single-lung or double-lung replacement. In a single-lung transplant, only one lung from a deceased donor is provided to the recipient. In a double-lung transplant, both the recipient's lungs are removed and replaced by the donor's lungs. In a lobar transplant, a lobe of the donor’s lung is excised, sized appropriately for the recipient’s thoracic dimensions, and transplanted. Donors for lobar transplant have primarily been living-related donors, with one lobe obtained from each of two donors (e.g., mother and father) in cases for which bilateral transplantation is required. There are also cases of

cadaver lobe transplants. Combined lung-pancreatic islet cell transplant is being studied for patients with cystic fibrosis.[2]

Since 2005, potential recipients have been ranked according to the Lung Allocation Score (LAS).[3] Patients 12 years of age and older receive a score between 1 and 100 based on predicted survival after transplantation reduced by predicted survival on the waiting list; the LAS takes into consideration the patient's disease and clinical parameters. In 2010, a simple priority system was implemented for children younger than age 12 years. Under this system, children younger than 12 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.

MEDICAL POLICY CRITERIA

I. Lung transplantation may be considered **medically necessary** for carefully selected patients with irreversible, progressively disabling, end-stage pulmonary disease unresponsive to maximum medical therapy.

II. A lobar lung transplant from a living or deceased donor may be considered **medically necessary** for carefully selected patients with end-stage pulmonary disease.

POLICY GUIDELINES

End-stage pulmonary disease may include, but is not limited to the following diagnoses:

Alpha-1 antitrypsin deficiency
Bilateral bronchiectasis
Bronchiolitis obliterans
Bronchopulmonary dysplasia
Chronic obstructive pulmonary disease
Cystic fibrosis (both lungs to be transplanted)
Eisenmenger's syndrome
Emphysema
Eosinophilic granuloma
Idiopathic/interstitial pulmonary fibrosis
Lymphangiomyomatosis
Postinflammatory pulmonary fibrosis
Primary pulmonary hypertension
Pulmonary hypertension due to cardiac disease
Recurrent pulmonary embolism
Sarcoidosis
Scleroderma

SCIENTIFIC EVIDENCE

Literature Appraisal

Due to the nature of the population, there are no randomized controlled trials (RCTs) that compare lung transplantation with alternatives. Systematic reviews are based on case series and registry data. The extant RCTs compare surgical technique, infection prophylaxis, or immunosuppressive therapy and are not germane to this policy. The following is a summary of the evidence based on registries, case series, and expert opinion.

Survival

The Registry of the International Society for Heart and Lung Transplantation (ISHLT) had reports from centers around the world of 3,272 lung transplants performed in 2009.[4] The overall median survival of patients who underwent lung transplantation between 1994 and June 2010 was 5.5 years. In the first 30 days after transplantation and the first year, the major reported causes of mortality were graft failure and non-cytomegalovirus (CMV) infections. Beyond the first year, the most common reported causes of mortality were bronchiolitis obliterans and non-CMV infections. Over time, the proportion of patients who died from malignancies increased; malignancies accounted for 15% of all deaths between 5 and 10 years after transplant. Authors of a 2009 review of the current status of lung transplantation observed that while transplantation can prolong survival, survival statistics for lung transplantation are not as favorable as in patients receiving other solid organ transplants.[5]

In 2009, Thabut and colleagues reported on a comparison of patients undergoing single- and double-lung transplantation for idiopathic pulmonary fibrosis.[6] A retrospective review was conducted of 3,327 patients with data in the UNOS registry. More patients underwent single-lung as compared to double-lung transplant (64.5 vs. 35.5%, respectively). Median survival time was greater for the double-lung group at 5.2 years (95% confidence interval [CI]: 4.3 to 6.7 years) versus 3.8 years (95% CI: 3.6 to 4.1 years; $p<0.001$). After adjustment for baseline differences, however, survival times were not statistically different. The authors concluded that overall survival did not differ between the 2 groups: single-lung transplants offered improved short-term survival but long-term harm, whereas double-lung transplant increased short-term harm but was associated with a long-term survival benefit.

Patient Selection

In 2008, Kozower and colleagues performed a retrospective cohort study using data from 5 academic medical centers to evaluate the impact of a new lung allocation score on short-term outcomes after lung transplantation.[7] (This lung allocation score 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 patients who received transplants on the basis of the new lung allocation scores (May 4, 2005 to May 3, 2006) with those of 171 patients 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.

In 2010, Yusen and colleagues reviewed the effect of the Lung Allocation Score (LAS) on lung transplantation by comparing statistics for the period before and after its implementation in 2005.[8] Other independent changes in clinical practice, which may affect outcomes over the same period of time, include variation in immunosuppressive regimens, an increased supply of donor lungs, changes in diagnostic mix, and increased consideration of older recipients. Deaths on the waiting list declined following implementation of the LAS system, from approximately 500 per 5,000 patients to 300 per 5,000 patients. However, it is expected that implementation of the LAS affected patient characteristics of transplant applicants. One-year survival post-transplantation did not improve after implementation of the LAS system: patient survival data before and after are approximately 83%.

In a recent study by Gries and colleagues, pre-transplant characteristics of 10,128 patients from the Organ Procurement and Transplantation Network (OPTN) database were examined to understand how well LAS post-transplant survival model parameters predict 1 and 5 year survival.[9] Authors concluded that the LAS system and pre-transplant characteristics in general did not predict long term 1- or 5-year survival better than chance.

In 2011, Russo and colleagues analyzed a dataset of 6,082 patients who received a lung transplant between May 4, 2005 and May 4, 2009 in order to describe outcomes and estimate the survival benefit based upon patient lung allocation score.[10] Authors found that although lower priority patients comprise the majority of transplants, mid-priority groups with LAS of 50-79, seemed to achieve the greatest survival benefit from transplantation (2.81-3.49 years). Patients with the highest and lowest LAS score achieved the least survival benefit; however, it was noted that patients with high allocation scores were expected to have worse survival and that patients with lower LAS had the lowest risk of death on the waiting list. Data suggested that transplant centers may be justified in considering patients for lung transplantation who had a mid-range allocation scores before patients with the highest and lowest scores.
Conclusion

Although long-term data is lacking, the Lung Allocation Scoring system appear to aid in selection and prioritization of patients for transplant.

Pediatric Considerations

In 2012, Benden and colleagues reviewed pediatric lung transplants that have been reported to the international registry.[11] Pediatric patients are defined as those younger than 18 years of age. The authors noted an increase in the number of pediatric lung transplants in recent years; there were 126 transplants in 2010 compared to 73 in 2000. In contrast to adult patients, the most common indication for pediatric patients was cystic fibrosis, 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 has improved in the recent era, and 5-year survival is 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%. Patients 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-CMV infection and graft failure were the 2 leading causes of death. Bronchiolitis obliterans syndrome was the major cause of death beyond 3 years after transplantation.

Potential Contraindications

Malignancy

Concerns regarding a potential recipient's history of cancer have been based on the observation of significantly increased incidence of cancer in kidney transplant patients.[12] For renal transplant patients who had a malignancy treated prior to transplant, the incidence of recurrence ranged from zero to more than 25%, depending on the tumor type.[13,14] However, it should be noted that the availability of alternative treatment strategies informs recommendations for a waiting period following high-risk malignancies: in renal transplant, a delay in transplantation is possible due to dialysis; end-stage lung disease patients may not have an option to defer.

A 2012 study reported on outcomes in patients with lung cancer who were lung transplant recipients.[15] Ahmad and colleagues identified 29 individuals in the UNOS database who underwent lung transplantation for advanced bronchoalveolar carcinoma (BAC). These patients represented 0.13% of the 21,553 lung transplantations during the study period. BAC and general lung transplant recipients had similar survival rates: the 30-day mortality rate was 7% versus 10% (p=0.44) and 5-year survival rate was 50% versus 57% (p=0.66), respectively.

HIV

Solid organ transplant for patients who are human immunodeficiency virus (HIV)-positive has been controversial, due to the long-term prognosis for HIV positivity and the impact of immunosuppression on HIV disease. Although HIV-positive transplant recipients may be of research interest at some transplant centers, the minimal data regarding long-term outcome in these patients primarily consist of case reports and abstract presentations of liver and kidney recipients. Nevertheless, some transplant surgeons would argue that HIV positivity is no longer an absolute contraindication to transplant due to the advent of highly active antiretroviral therapy (HAART), which has markedly changed the natural history of the disease.

As of November 2010, the Organ Procurement Transplantation Network (OPTN) policy on HIV status in recipients states: "A potential candidate for organ transplantation whose test for HIV is positive should not be excluded from candidacy for organ transplantation unless there is a documented contraindication to transplantation based on local policy."[16]

Other Infections

Infection with *Burkholderia cenocepacia* is associated with increased mortality in some transplant centers, a factor that may be taken into account when evaluating overall risk for transplant survival.[17] Two papers published in 2008 evaluated the impact of infection with various species of *Burkholderia* on outcomes for lung transplantation for cystic fibrosis. In a study published by Murray and colleagues, multivariate Cox survival models assessing hazard ratios (HRs) were applied to 1,026 lung transplant candidates and 528 transplant recipients.[18] Of the transplant recipients, 88 were infected with *Burkholderia*. Among transplant recipients infected with *Burkholderia cenocepacia*, only those infected with nonepidemic strains (n=11) had significantly greater post-transplant mortality than uninfected patients (HR: 2.52; 95% confidence interval [CI: 1.04-6.12; p=0.04). Transplant recipients infected with *Burkholderia gladioli* (n=14) also had significantly greater post-transplant mortality than uninfected patients (HR: 2.23; 95% CI: 1.05-4.74; p=0.04). When adjustments for specific species/strains were included, lung allocation scores of *Burkholderia multivorans*-infected transplant candidates were comparable to uninfected candidate scores, and scores for patients infected with non-

epidemic *B cenocepacia* or *B gladioli* were lower. In a smaller study of 22 patients colonized with *Burkholderia cepacia* complex who underwent lung transplantation in two French centers, 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*).[19]

In 2012, Shields and colleagues reported on infections in 596 consecutive lung transplant recipients treated at a single center occurring in the first 90 days after transplantation.[20] A total of 109 patients (18%) developed 138 *Staphylococcus aureus* infections. The most common type of infection was pneumonia (66 of 138, 48%) followed by tracheobronchitis (36 of 138, 26%) and bacteremia (17 of 138, 12%). Thirteen of 109 (12%) of patients with *Saureus* infection died within 90 days of the onset of infection. The 1-year mortality rate was higher for patients with *Saureus* pneumonia (19 of 66, 29%) but not *Saureus* tracheobronchitis (8 of 36, 22%) compared with uninfected patients (85 of 487, 17%).

Pinney and colleagues published a retrospective review of invasive fungal infection rates in lung transplantation patients without cystic fibrosis treated at a single center.[21] Patients were followed for a median of 34 months. Invasive fungal infections were identified in 22 of 242 (9.1%) patients. *Aspergillus* infections were most common, occurring in 11 of 242 (4.5%) of patients. There were also 7 cases (3%) of *Candida* infection. Survival rates did not differ significantly in patients with invasive fungal infections compared to the entire cohort of patients. For example, 3-year survival was 50% among patients with invasive fungal infection and 66% in the entire cohort, p=0.66. The authors did not compare survival in patients with invasive fungal infections to survival only in those without invasive fungal infections.

Coronary Artery Disease (CAD)

In 2011, Sherman and colleagues reported on outcomes in 27 patients with CAD at a single center who underwent lung transplantation and coronary revascularization.[22] Patients needed to be otherwise considered good candidates for transplantation and have discrete coronary lesions (at least 50% in the left main artery or at least 70% in other major vessels) and preserved ejection fraction. Thirteen patients had single-lung transplantation and 14 had double-lung transplantation. Outcomes were compared with a control group of 81 patients without CAD who underwent lung transplantation; patients were matched for age, diagnosis, lung allocation score and type of procedure. During a mean follow-up of 3 years, 9 of 27 (33%) patients with CAD and 28 of 81 (35%) without CAD died, p=0.91. *Bronchiolitis obliterans* and infection were the primary causes of death. There was no significant difference between groups in a composite outcome of adverse cardiac events (defined as acute coronary syndrome, redo revascularization or hospital admissions for congestive heart failure), p=0.80.

Lobar Lung Transplantation

Several case series have reported outcomes after lobar lung transplants in both children and adults. In 2005, Barr and colleagues reported on experience performing living donor lobar lung transplants in the U.S.[23] Ninety patients were adults and 43 were children. The primary indication for transplantation (86%) was cystic fibrosis. At the time of transplantation, 67% of patients were hospitalized and 20% were ventilator dependent. Overall recipient actuarial survival at 1-, 3- and 5-years was 70%, 54% and 45%, respectively. There was not a statistically significant difference in actuarial survival between adults and children who underwent transplantation. Moreover, survival rates were similar to the general population of lung transplant recipients. The authors also reported that rates of postoperative pulmonary function in patients surviving more than 3 months post-transplant were comparable to rates in cadaveric lung transplant recipients.

In 2012, a program in Japan reported on 14 critically ill patients who had undergone single living-donor lobar lung transplants; there were 10 children and 4 adults.[24] Patients were followed for a mean 45 months. The 3-year survival rate was 70% and the 5-year survival was 56%. Severe graft dysfunction occurred in 4 patients. Mean forced vital capacity (FVC) was found to be lower in patients experiencing severe graft dysfunction compared to the other patients, mean FVC was 54.5% and 66.5%, respectively. The authors stated that this suggests size mismatching in the patients with severe graft dysfunction. Also in 2012, Inci and colleagues published data on 23 patients in Switzerland who received bilateral lobar lung transplants.[25] The mean age was 41 years (range: 13 to 66 years). Survival at 1 and 2 years was 82% and 64%, respectively; survival rates were comparable with 219 patients who underwent bilateral lung transplantation during the same time period (p=0.56).

A review article by Date stated that, as of 2011, approximately 400 living-donor lobar lung transplants have been performed worldwide.[26] Procedures in the U.S. decreased after 2005 due to changes in the lung allocation system. The author stated that size matching between donor and recipient is important and that, to some extent, size mismatching (oversized or undersized grafts) can be overcome by adjusting surgical technique.

Clinical Practice Guidelines

International Society for Heart and Lung Transplantation (ISHLT)

In 2006, the Pulmonary Scientific Council of the ISHLT published consensus-based guidelines on selection of lung transplant candidates[27] The guidelines state that, "Lung transplantation is now a generally accepted therapy for the management of a wide range of severe lung disorders, with evidence supporting quality of life and survival benefit for lung transplant recipients. However, the number of donor organs available remains far fewer than the number of patients with end-stage lung disease who might potentially benefit from the procedure. It is of primary importance, therefore, to optimize the use of this resource, such that the selection of patients who receive a transplant represents those with realistic prospects of favorable long-term outcomes. There is a clear ethical responsibility to respect these altruistic gifts from all donor families and to balance the medical resource requirement of one potential recipient against those of others in their society. These concepts apply equally to listing a candidate with the intention to transplant and potentially de-listing (perhaps only temporarily) a candidate whose health condition changes such that a successful outcome is no longer predicted."

Global Initiative for Chronic Obstructive Lung Disease (GOLD)

In 2011 GOLD committee members performed a literature search and developed guidelines regarding the diagnosis, management and prevention of chronic obstructive pulmonary disease.[28] The committee suggested that in carefully selected patients with COPD, lung transplantation has been shown to improve quality of life and functional capacity. The guidelines state, "criteria for referral for lung transplantation include COPD with a BODE index exceeding 5. Recommended criteria for listing include a BODE index of 7-10 and at least one of the following: history of exacerbation associated with acute hypercapnia [PaCO2 >6.7 kPa (50 mmHg)]; pulmonary hypertension, cor pulmonale, or both despite oxygen therapy; and FEV_1<20% predicted with either DLCO <20% predicted or homogenous distribution of emphysema." These recommendations were made on the basis of fairly weak evidence collected from observational studies; however, randomized controlled trials are unlikely in this patient population.

Summary

The literature on lung and lobar lung transplantation, which consists of case series and registry data, demonstrates that lung and lobar lung transplantation provides a survival benefit in appropriately selected patients and thus may be considered medically necessary. It may be the only option for some patients with end-stage lung disease.

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CROSS REFERENCES

Heart/Lung Transplant, Transplant, Policy No. 3

CODES	NUMBER	DESCRIPTION
CPT	32850	Donor pneumonectomy(ies) (including cold preservation), from cadaver donor
	32851	Lung transplant, single; without cardiopulmonary bypass
	32852	; with cardiopulmonary bypass
	32853	Lung transplant, double (bilateral, sequential, or en bloc); without cardiopulmonary bypass
	32854	; with cardiopulmonary bypass
	32855	Backbench standard preparation of cadaver donor lung allograft prior to transplantation, including dissection of allograft from surrounding tissues to prepare pulmonary venous/atrial cuff, pulmonary artery, and bronchus, unilateral
	32856	; bilateral
HCPCS	S2060	Lobar lung transplantation
	S2061	Donor lobectomy (lung) for transplantation, living donor