02-30000-10 Original Effective Date: 12/07/00 Reviewed: 07/25/24 Revised: 08/15/24

Subject: Lung and Lobar Lung Transplant

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

Position Statement	Billing/Coding	Reimbursement	Program Exceptions	<u>Definitions</u>	Related Guidelines
Other	<u>References</u>	<u>Updates</u>			

DESCRIPTION:

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

End-stage lung disease may derive from different etiologies. The most common indications for lung transplantation are chronic obstructive pulmonary disease, idiopathic pulmonary fibrosis, cystic fibrosis, a1-antitrypsin deficiency, and idiopathic pulmonary arterial hypertension.

Before consideration for transplant, candidates should be receiving maximal medical therapy, including oxygen supplementation, or surgical options.

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 in cases for which bilateral transplantation is required. There are also cases of cadaver lobe transplants.

Bilateral lung transplantation is typically required when chronic lung infection and disease is present (ie, associated with cystic fibrosis and bronchiectasis). Some, but not all, cases of pulmonary hypertension will require bilateral lung transplantation. Bronchiolitis obliterans is associated with chronic lung transplant rejection, and thus may be the etiology of a request for lung retransplantation.

Summary and Analysis of Evidence: International registry data on a large number of patients receiving lung transplantation (>50,000) found relatively high patient survival rates (89% at 3 months, 80% at 1 year, 65% at 5 years, 32% at 10 years). In patients who survived at least 1 year, median survival was 8 years. After adjusting for potential confounding factors, survival did not differ significantly after single-lung or double-lung transplant. A subgroup analysis of an international registry study found decreased

survival for adolescent patients, especially between 15 and 19 years of age, who received lung transplantation, but the study was limited by inclusion bias, lack of data on mortality, differences in treatment regimens, and rates of graft dysfunction (Yu et al, 2019; Paraskeva et al, 2018; Goldfarb et al, 2016; Yusen, Edwards et al, 2016; Black et al, 2014; Shafii et al, 2014; Thabut et al, 2010; Yusen, Shearon et al, 2010).

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

In 2021, the International Society for Heart and Lung Transplantation published updated consensusbased guidelines on the selection of lung transplant candidates. The guidelines states that "(I)ung transplantation should be considered for adults with chronic, end-stage lung disease who have a high (>50%) risk of death from lung disease within 2 years if lung transplantation is not performed; and who have a high (>80%) likelihood of 5-year post-transplant survival from a general medical perspective, provided that there is adequate graft function." The guideline also notes risk factors to be considered in the evaluation of transplant candidates, along with pediatric and disease-specific considerations (Leard et al, 2021).

There is less data on lung lobar transplants than on whole-lung transplants. The available data reported in case series have suggested reasonably similar survival outcomes, and lung lobar transplants may be the only option for patients unable to wait for a whole-lung (Date et al, 2015; Slama et al, 2014; Barr et al, 2005). A 2017 systematic review found 1-year survival rates for lung lobar transplants ranging from 50% to 100% (Eberlein et al, 2017).

Registry data and case series have demonstrated favorable outcomes with lung retransplantation in certain populations, such as in patients who meet criteria for initial lung transplantation (Yusen, Christie et al, 2013; Kilic et al, 2013; Kawut SM, 2011). Given the exceedingly poor survival without retransplantation of patients who have exhausted other treatments, evidence of a moderate level of posttransplant survival is sufficient to suggest treatment efficacy in this patient population. The International Society for Heart and Lung Transplantation Registry contained data on 2273 retransplantation patients performed through June 2015 (4.4% of lung transplantations) (Yusen, Edwards, 2016). The major causes of death in the first 30 days after retransplantation were graft failure and non-CMV infection, followed by multiorgan failure, cardiovascular causes, and technical factors related to the transplant procedure. Beyond the first year, the most commonly reported causes of mortality were obstructive bronchiolitis/bronchiolitis obliterans, graft failure, and non-CMV infections.

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

POSITION STATEMENT:

Certificate of Medical Necessity

Submit a completed Certificate of Medical Necessity (CMN) along with your request to expedite the medical review process.

- 1. Click the link Solid Organ Transplant under Certificates of Medical Necessity in the side navigation of this page to access the form.
- 2. Complete all fields on the form thoroughly.
- 3. Print and submit a copy of the form with your request.

Note: Florida Blue regularly updates CMNs. Ensure you are using the most current copy of a CMN before submitting to Florida Blue.

Lung transplantation **meets the definition of medical necessity** for carefully selected individuals with irreversible, progressively disabling, end-stage pulmonary disease, unresponsive to maximum medical therapy.

A lobar lung transplant from a living or deceased donor **meets the definition of medical necessity** for carefully selected candidates with end-stage pulmonary disease.

Lung or lobar lung **re**transplantation **meets the definition of medical necessity** after a failed lung or lobar lung transplant in individuals who meet criteria for lung transplantation.

Lung and lobar lung transplantation is considered **experimental or investigational** in all other situations, as available clinical evidence does not support safety and effectiveness.

Potential contraindications to lung and lobar lung transplantation (subject to the judgment of the transplant center) include:

- Known current malignancy, including metastatic cancer
- Recent malignancy with high risk of recurrence
- Untreated systemic infection making immunosuppression unsafe, including chronic infection
- Other irreversible end-stage disease not attributed to lung disease
- History of cancer with a moderate risk of recurrence
- Systemic disease that could be exacerbated by immunosuppression
- Psychosocial conditions or chemical dependency affecting ability to adhere to therapy
- Coronary artery disease (CAD) not amenable to percutaneous intervention or bypass grafting, or associated with significant impairment of left ventricular function
- Colonization with highly resistant or highly virulent bacteria, fungi or mycobacteria

BILLING/CODING INFORMATION:

CPT Coding:

32850	Donor pneumonectomy (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 Coding:

S2060	Lobar lung transplantation
S2061	Donor lobectomy (lung) for transplantation, living donor

REIMBURSEMENT INFORMATION:

None applicable.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline reviewed date.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at <u>Coverage</u> <u>Protocol Exemption Request</u>.

DEFINITIONS:

Bronchiectasis: chronic dilatation of the bronchi marked by unpleasant breath and paroxysmal coughing with expectoration of mucopurulent matter.

Cystic fibrosis: a generalized autosomal recessive disorder, characterized by signs of chronic pulmonary disease due to excess mucous production in the respiratory tract in addition to other pathological abnormalities.

Dyspnea: difficult or labored breathing.

Pneumonectomy: the excision of lung tissue, especially of an entire lung.

Pulmonary fibrosis: chronic inflammation and progressive fibrosis of the pulmonary alveolar walls with steadily increasing dyspnea, resulting in death from lack of oxygen or right heart failure.

RELATED GUIDELINES:

Heart and Lung Transplant, 02-33000-24

OTHER:

Florida Statute 765.523 Discrimination in access to anatomical gifts and organ transplants prohibited. (excerpt)

(3)(d) "Organ transplant" means the transplantation or transfusion of a part of a human body into the body of another individual for the purpose of treating or curing a medical condition.

Florida Statute 627.64197 Coverage for organ transplants.—A health insurance policy issued, delivered, or renewed on or after July 1, 2020, in this state by an insurer which provides coverage for organ transplants on an expense-incurred basis may not deny coverage for an organ transplant solely on the basis of an insured's disability. This section may not be construed to require such insurer to provide coverage for an organ transplant that is not medically necessary. For purposes of this section, the term "organ transplant" has the same meaning as in s. 765.523.

Florida Statute 627.65736 Coverage for organ transplants.—A group health insurance policy delivered, issued, or renewed on or after July 1, 2020, in this state by an insurer or nonprofit health care services plan which provides coverage for organ transplants on an expense-incurred basis may not deny coverage for an organ transplant solely on the basis of an insured's disability. This section may not be construed to require such insurer or nonprofit health care service plan to provide coverage for an organ transplant that is not medically necessary. For purposes of this section, the term "organ transplant" has the same meaning as in s. 765.523.

Florida Statute 641.31075 Coverage for organ transplants.—A health maintenance contract issued or renewed on or after July 1, 2020, in this state by a health maintenance organization which provides coverage for organ transplants may not deny coverage for an organ transplant solely on the basis of a subscriber's disability. This section may not be construed to require such health maintenance organization to provide coverage for an organ transplant that is not medically necessary. For purposes of this section, the term "organ transplant" has the same meaning as in s. 765.523.

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 07/25/24.

GUIDELINE UPDATE INFORMATION:

12/07/00	New Medical Coverage Guideline.
09/01/01	HCPCS coding changes.
12/15/02	Reviewed and revised; statement was added regarding transplant facilities.
11/15/04	Scheduled review; added statement regarding organ transplants in HIV-positive
	recipients.
06/15/05	Revision to guideline, consisting of removal of investigational statement regarding HIV-
	positive recipients.
06/15/06	Scheduled review; no change in coverage statement.
06/15/07	Scheduled review (consensus); reformatted guideline. Updated references.
07/15/08	Scheduled review; no change in position statement. Update references.
07/15/09	Scheduled review; no change in position statement. Update references.
10/15/10	Revision; related ICD-10 codes added.
10/01/11	Revision; deleted ICD9 code 516.3; added ICD9 code 516.69.
04/01/12	Revision; updated ICD10 coding with new and revised codes.
06/15/12	Revision; added Medicare Advantage program exception for extracorporeal
	photopheresis (ECP) following lung allograft transplantation. Updated references.
07/15/14	Scheduled review. Revised description, position statement, and program exceptions
	section. Updated references.
12/15/19	Scheduled review. Revised description, maintained position statement, and updated
	references.

07/01/20	Revision: added Florida statute language regarding discrimination in access to anatomical
	gifts and coverage of organ transplants. Updated references.
10/15/20	Revision. Deleted UNOS guidelines criterion.
09/15/21	Scheduled review. Revised description and maintained position statement. Updated
	references.
05/23/23	Update to Program Exceptions section.
09/15/23	Scheduled review. Maintained position statement and updated references.
08/15/24	Scheduled review. Revised description, maintained position statement and updated
	references.