Lung and Lobar Lung Transplant*

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Original Effective Date: November 2009
Reviewed: November 2020
Revised: November 2020

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Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

This Medical Policy document describes the status of medical technology at the time the document was developed. Since that time, new technology may have emerged or new medical literature may have been published. This Medical Policy will be reviewed regularly and be updated as scientific and medical literature becomes available, therefore policies are subject to change without notice.

DESCRIPTION

The primary goal of lung transplantation is extended survival. For most patient’s lung transplant is a palliative rather than curative treatment intended for patients with end-stage lung disease who have failed to respond to alternative medical or surgical treatment.

Lung transplantation (single or double)
Lung transplantation involves either single-lung or double-lung replacement. One or both lungs are transplanted from a donor with pronounced brain death into the chest cavity of the recipient.

Lobar lung transplant
A lobar lung transplant refers to the transplant of a lobe excised from the donor's lung that is sized appropriately for the recipient's thoracic dimensions. Lobar lung transplant donors are primarily living related donors, with one lobe obtained from each of two donors in cases where a bilateral transplant is required.
The type of lung transplant is based upon the patient’s condition and the indication for transplant. Living-donor lobar-lung transplant refers to the transplantation of either the right or left lower lobe from one or two healthy donors to replace one or both lungs. The procedure was devised to assist in alleviating the limited availability of cadaveric lungs and thereby prolong survival in patients who are likely to die before a cadaveric organ becomes available.

Registry data and case series reports have demonstrated favorable outcomes with lung retransplantation in certain populations, such as in patients who meet criteria for initial lung transplantation.

**Professional Guidelines and Position Statements**

**American College of Cardiology/American Heart Association Task Force on Practice Guidelines (ACC/AHA):** The 2018 ACC/AHA guideline for the management of adults with congenital heart disease (ACHD) stated in patients with ACHD and Eisenmenger syndrome exhibiting deteriorating functional ability, mechanical circulatory and pulmonary support, lung transplantation with concomitant repair of anatomic cardiovascular defects, and heart–lung transplantation have been applied.

**Regulatory Status**

The U.S. Food and Drug Administration regulates human cells and tissues intended for implantation, transplantation, or infusion through the Center for Biologics Evaluation and Research, under Code of Federal Regulation Title 21, parts 1270 and 1271. Lung transplants are included in these regulations.

In November 2016, the Lung Assist Perfusion System received a CE mark certification permitting commercial distribution in Europe. FDA has not yet cleared the Lung Assist Perfusion System for use in the United States.

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<td>Lung or lobar lung transplantation and retransplantation may be considered <strong>medically necessary</strong> in patients with end-stage disease of lung parenchyma, airway and pulmonary vasculature that is not amenable to maximum alternative medical and surgical therapies when one the following criteria are met:</td>
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  - Severe, progressive symptoms with a functional status of New York Heart Association (NYHA) class III or IV despite optimal medical management, resulting in an unacceptable quality of life.
  - Patients must meet United Network for Organ Sharing guidelines for a Lung Allocation Score greater than zero.
Categories of lung disease for which transplant may be indicated include, but are not limited to:

- Restrictive lung diseases such as idiopathic pulmonary fibrosis, pulmonary fibrosis from other causes, interstitial lung disease, sarcoidosis, asbestosis
- Chronic obstructive lung diseases such as emphysema, alpha-1 antitrypsin deficiency, chronic bronchitis, bronchiolitis obliterans, lymphangioleiomyomatosis
- Septic lung diseases such as cystic fibrosis, bronchiectasis
- Pulmonary vascular diseases such as pulmonary hypertension, Eisenmenger syndrome, recurrent pulmonary embolism

Lung and lobar lung transplant and retransplant is considered not medically necessary for patients with the following contraindications:

- Persistent, recurrent or unsuccessfully treated major or systemic infections, making immunosuppression unsafe
- Systemic illness or comorbidities that would be expected to substantially negatively impact the successful completion and/or outcome of transplant surgery or would be exacerbated by immunosuppression
- Untreatable advanced dysfunction of another organ system such as heart, liver, or kidney disease
- Coronary artery disease not amenable to percutaneous intervention or bypass grafting, or associated with significant impairment of left ventricular function
- Significant chest wall deformity
- A pattern of noncompliance which would place a transplanted organ at serious risk of failure
- Current malignancy

The evaluation of a transplant candidate who has a history of cancer must consider the prognosis and risk of recurrence from available information including tumor type and stage, response to therapy, and time since therapy was completed. Although evidence is limited, patients in whom cancer is thought to be cured should not be excluded from consideration for transplant. UNOS has not addressed malignancy in current policies.

The United Network for Organ Sharing (UNOS) believes that asymptomatic HIV-positive patients should not necessarily be excluded for candidacy for organ transplantation, stating, “A potential candidate for organ transplantation whose test for HIV is positive but who is in an asymptomatic state should not necessarily be excluded from candidacy for organ transplantation, but should be advised that he or she may be at increased risk of morbidity and mortality because of immunosuppressive therapy.” In 2001, the Clinical Practice Committee of the American Society of Transplantation proposed that the presence of AIDS could be considered a contraindication to kidney transplant unless the following criteria were present. These criteria may be extrapolated to other potential organ transplants:
- CD4 count ≥ 200 cells/mm-3 for > 6 months
- HIV-1 RNA undetectable
- On stable anti-retroviral therapy > 3 months
- No other complications from AIDS (e.g., opportunistic infection including aspergillus, tuberculosis, coccidioses mycosis, resistant fungal infections, Kaposi’s sarcoma, or other neoplasm)
- Meeting all other criteria for organ transplantation

It is likely that each individual transplant center will have explicit patient selection criteria for HIV-positive patients.

Lung xenotransplantation (e.g., porcine xenografts) is considered **investigational** for any pulmonary conditions because of insufficient evidence in the peer-reviewed literature.

### PROCEDURE CODES AND BILLING GUIDELINES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnosis codes.

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

### SELECTED REFERENCES

- Steinman TI, Becker BN, Frost AE et al. Clinical Practice Committee, American Society of Transplantation. Guidelines for the referral and management of patients


POLICY HISTORY

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<tr>
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New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

Wellmark Blue Cross and Blue Shield
Medical Policy Analyst
PO Box 9232
Des Moines, IA 50306-9232

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