

MEDICAL POLICY



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Product Disclaimer	<ul style="list-style-type: none"> • <i>Services are contract dependent; if a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.</i> • <i>If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.</i> • <i>If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.</i> • <i>If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.</i> • <i>If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.</i>

POLICY STATEMENT

- I. Based upon our criteria and assessment of the peer-reviewed literature, lung transplantation has been medically proven to be effective and, therefore, is considered **medically appropriate** for carefully selected candidates who have irreversible, progressively disabling, end-stage pulmonary disease and who meet **ALL** of the following criteria:
- Adequate cardiac status,
 - Absence of infection, or absence of extrapulmonary infection in patients with cystic fibrosis,
 - No history of malignancy within five years of transplantation, excluding non-melanomatous skin cancers;
 - Documentation of patient compliance with medical management.

Indications include, but are not limited to, the following:

- Bilateral bronchiectasis;
- Congenital bronchiectasis;
- Alpha-1 antitrypsin deficiency;
- Primary pulmonary hypertension;
- Cystic fibrosis;
- Bronchopulmonary dysplasia;
- Idiopathic pulmonary fibrosis;
- Interstitial pulmonary fibrosis;
- Sarcoidosis;
- Scleroderma;
- Lymphangiomyomatosis;
- Emphysema;
- Eosinophilic granuloma;
- Bronchiolitis obliterans;
- Recurrent pulmonary embolism;

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- P. Chronic obstructive pulmonary disease;
- Q. Tuberculous fibrosis of lung;
- R. Pneumoconiosis and other lung diseases due to external agents;
- S. Eisenmenger's syndrome.

II. Recipient Selection Guidelines

Each recipient considered for transplantation should have an evaluation completed by the transplant center, for potential difficulties that would complicate and diminish the success of transplantation. Consideration will be given to the patient's risk of death without transplantation, along with the presence and severity of potential contraindications to transplantation.

- A. The following general medical conditions can have an impact on the long-term outcome of lung transplant recipients. Other medical conditions, when they have not resulted in organ damage, are generally acceptable in candidates for lung transplantation (e.g., systemic hypertension, diabetes mellitus, peptic ulcer disease) and should be optimally treated and well-controlled. In the presence of any comorbid medical condition with the potential for end-organ damage, a careful search should be made for evidence of organ dysfunction.
 - 1. Current use of corticosteroids is not a contraindication to transplantation. However, all attempts to discontinue these drugs or at least reduce the dose to less than or equal to 20 mg per day of prednisolone or prednisone should be made.
 - 2. Nutritional issues are important predictors of surgical outcome. Patients with an ideal body weight less than 70% or greater than 130% require either weight gain or weight loss to become eligible for transplant.
 - 3. Substance abuse issues need to be addressed prior to lung transplantation. Candidates must have been free of substance addiction (e.g., alcohol, tobacco, narcotics) for at least six months. Appropriate preoperative biochemical monitoring is recommended in at-risk patients.
 - 4. Psychosocial problems that are unable to be resolved and that have a high likelihood of having a negative impact on the patient's outcome (e.g., poorly controlled major psycho-affective disorder, inability to comply with complex medication regimen) are a relative contraindication. A documented history of noncompliance with medical care or treatment plans, even in the absence of a documented psychiatric condition, is a relative contraindication.
 - 5. Colonization with fungi or atypical mycobacteria is not an absolute contraindication to transplantation. Cases should be considered on an individual basis. Special care should be taken when a unilateral transplant is considered. When possible, pre-operative attempts to eradicate colonization with antibiotic therapy are appropriate. Adequately treated mycobacterium (M) tuberculosis is not a contraindication to lung transplantation.
- B. Lung and lobar transplantation in the context of asymptomatic HIV infection is rapidly evolving in the setting of highly active antiretroviral therapy (HAART). Currently, the United Network for Organ Sharing (UNOS) states that asymptomatic HIV-positive patients should not necessarily be excluded for candidacy for organ transplantation. In 2001, the Clinical Practice Committee of the American Society of Transplantation proposed that the presence of AIDS could be considered a contraindication to lung and lobar transplant, unless the patient meets **ALL** of the following criteria:
 - 1. CD4 count greater than 200 cells/mm³.
 - 2. Undetectable HIV-1RNA.
 - 3. On stable anti-retroviral therapy for greater than three months.
 - 4. No other complications from AIDS (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidioidomycosis; resistant fungal infections, Kaposi's sarcoma, or other neoplasm); **and**
 - 5. All other criteria for transplantation.
- C. Contraindications to Lung Transplantation
 - 1. Absolute Contraindications include:
 - a. Infection with HIV, unless **ALL** of the following criteria are met:

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- i. CD4 count greater than 200 cells/mm³;
 - ii. HIV-1RNA undetectable;
 - iii. On stable anti-retroviral therapy greater than three (3) months;
 - iv. No other complications from AIDS (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidioidomycosis, resistant fungal infection, Kaposi's sarcoma, or other neoplasm); **and**
 - v. Meets all other criteria for transplantation;
 - b. Presence of malignancy (other than non-melanoma skin cancers), unless malignancy has been completely resected, or unless (upon medical review) it is determined that malignancy has been treated with small likelihood of recurrence and acceptable future risks; **and**
 - c. Progressive neuromuscular disease.
2. Relative Contraindications include:
Dysfunction of major organs, other than the lung. Renal dysfunction (e.g., creatinine clearance of 50 mg/ml/min), in particular, is a contraindication, because of the impact of immunosuppressive drugs on renal function. Patients with significant untreatable coronary artery disease or left ventricular dysfunction warrant consideration for heart-lung transplant.
- Other relative contraindications include:
- a. Hepatitis B antigen positivity;
 - b. Hepatitis C with biopsy-proven histologic evidence of liver disease;
 - c. Symptomatic osteoporosis. The potential risk to acceptable long-term outcomes should be assessed on a case-by-case basis. Both symptomatic and asymptomatic significant disease requires treatment that should be initiated prior to transplantation. Patients should be fully investigated and followed by appropriate objective measures (e.g., bone densitometry);
 - d. Severe musculoskeletal disease affecting the thorax (e.g., kyphoscoliosis); **and**
 - e. Requirement for invasive ventilation. Patients who are receiving non-invasive ventilatory support and who meet all other criteria are eligible for lung transplantation.

III. Living Donor Selection Guidelines

Each donor considered for transplantation should have an evaluation completed by the transplant center for potential difficulties that would complicate and diminish the success of transplantation.

Any person who gives consent to be a live organ donor should be competent, willing to donate, free from coercion, medically and psychologically suitable, fully informed of the risks and benefits as a donor, and fully informed of the risks, benefits, and alternative treatment available to the recipient. The benefits to both donor and recipient must outweigh the risks associated with the donation and transplantation of the living donor organ.

POLICY GUIDELINES

- I. Prior authorization requirements are contract dependent. Approvals for all transplants, including arrangements with an approved transplant center, may be required.
- II. Pre-transplant evaluation documentation should include the following clinical information (if testing is unable to be performed, the rationale for not performing the testing must be included in the documentation):
 - A. Clinical Evaluation:
 1. Confirmation of diagnosis;
 2. Identification of comorbidities;
 3. Treatment of co-morbidities;
 4. Current assessment of co-morbidities; **and**
 5. Consult notes (if applicable).
 - B. Psycho-Social Evaluation:
 1. Karnofsky performance score; and/or Palliative Performance Scale (PPS) score.

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2. Identification of stressors (family support, noncompliance issues, motivational issues, alcohol or substance abuse).

C. Oral Health Evaluation

D. Lab Tests:

1. CBC, metabolic profile;
2. Serologies: CMV; Hepatitis B and C; **and**
3. HIV Testing.

E. Cardiac Assessment:

1. 12 Lead EKG; and
2. Stress (exercise, nuclear, or dobutamine), **and**
3. Echo or MUGA Scan

F. Pulmonary Assessment:

1. Chest x-ray;
2. Pulmonary function tests (PFTs) for high-risk respiratory failure (COPD, emphysema, alpha 1-antitrypsin deficiency, hepatopulmonary syndrome, or significant smoking history); **and**
3. Low-dose screening CT for individuals considered high-risk for lung cancer (e.g., 20- to 30-pack history of smoking).

G. Age-appropriate Screening Tests:

Please refer to the U.S. Preventive Services Task Force (USPSTF) website for a list of age-appropriate screening guidelines. [<https://uspreventiveservicestaskforce.org/uspstf/>] accessed 03/26/24.

III. Re-Authorization

Transplant reauthorization must be completed annually while actively waiting for a transplant. Re-authorization documentation must be within the past eleven months (unless specified) and include the following clinical information (if testing is unable to be performed, the rationale must be included in the documentation). If your health condition has not changed from the previous year some testing would not be applicable.

A. Clinical Evaluation:

1. Updated list of diagnoses to include identification of comorbidities, current assessment, and treatment plan.
2. Specialty consultation notes (indicated by clinical presentation).

B. Current functional ability as evidenced by current Karnofsky performance score (KPS); and/or Palliative Performance Scale (PPS) score.

C. Follow-up Oral Health Exam

D. Lab Tests:

1. CBC, metabolic profile;
2. Serologies: CMV; Hepatitis B and C; **and**
3. HIV testing (indicated by clinical presentation)

E. Cardiac Assessment:

1. 12 Lead EKG (if applicable); and
2. Stress (exercise, nuclear, or dobutamine (indicated by clinical presentation)); **and**
3. Echo or MUGA Scan (indicated by clinical presentation).

F. Pulmonary Assessment:

2. Chest x-ray (indicated by clinical presentation)
3. Pulmonary function tests (PFTs) (indicated by clinical presentation)
4. Low-dose screening CT for individuals considered high-risk for lung cancer (e.g., 20- to 30-pack history of smoking)

G. Age-appropriate Screening Tests:

Please refer to the U.S. Preventive Services Task Force (USPSTF) website for a listing of age-appropriate screening guidelines. [<https://uspreventiveservicestaskforce.org/uspstf/>].accessed 03/21/24.

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DESCRIPTION

Lung transplantation offers carefully selected patients the only curative treatment for end-stage pulmonary parenchymal and vascular diseases. A lung transplant, either single or double, involves the surgical removal of a lung from one or more cadaveric or living donors and transplantation of the lung(s) into a recipient.

In an attempt to ease the shortage of available lungs for transplantation, especially lungs small enough to be suitable for children and adolescents, lobar transplants have been performed. In a lobar transplant, a lobe of the donor's lung is excised, sized appropriately for the recipient's thoracic dimensions, and transplanted. Although donors for lobar transplants have primarily been living relatives, there have been cases of cadaveric lobe transplants. In cases where a bilateral lobar transplant is required, one lobe is obtained from each of the two donors.

In 2005, the United Network for Organ Sharing (UNOS), a non-profit organization that contracts with the United States government to serve as the nation's organ procurement and transplantation network (OPTN), began to use a new lung allocation system for patients aged 12 years and older, based on wait list urgency and probability of prolonged survival following transplant. The system assigns a score using a candidate's diagnosis, New York Heart Association Class, use of a ventilator, diabetes treatment (if applicable), oxygen required at rest, and pulmonary function and laboratory values.

Lung candidates under the age of 12 are not prioritized by lung allocation scores. Instead, pediatric lung candidates are classified as Priority 1 or Priority 2, based on their medical condition. Patients who meet criteria reflecting a more urgent status are listed as Priority 1. All other lung candidates in this age range are Priority 2. A candidate's pediatric priority is used, along with blood type and distance from the donor hospital, to determine the order for making offers to lung candidates. The UNOS (OPTN) Board of Directors recently approved expanded geographic sharing, to direct all lungs from pediatric donors less than 18 years of age to child candidates less than 12 years of age within a 1,000-mile radius. This update seeks to maximize the availability of appropriately sized pediatric donor organs to pediatric candidates, and may especially benefit older children nearing age 12 who could accommodate lungs from smaller adolescent donors. The new policy change provides for broader sharing and also for ABO-incompatible transplants in children listed before their second birthday.

Candidates receive lung offers based mainly on their lung allocation scores or, for candidates younger than age 12 a pediatric priority status. Waiting time plays a very limited role, when allocating lungs to transplant candidates aged 12 years and older. Waiting time is used to break ties when two or more lung candidates have the same lung allocation score or pediatric priority status, and these candidates are in the same geographic zone. Transplant centers-need to update medical information every six months. As the lung allocation system uses medical information to compute lung allocation scores, it is important that transplant centers have the most current information and test results. Transplant centers may also update information in the system any time it is necessary to reflect a change in medical condition.

RATIONALE

Lung or lobar/lung transplantation represents the only curative approach for many carefully screened patients with end-stage pulmonary disease. Advances in donor and recipient selection, improved surgical techniques, new immunosuppressive drugs, and better management of infections have improved long-term survival.

Solid organ transplantation for candidates who are HIV-positive has long 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 a research interest of some transplant centers, the minimal data regarding long-term outcomes in these patients consists primarily 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 HAART, which has markedly changed the natural history of the disease. Furthermore, UNOS states that asymptomatic HIV-positive patients should not necessarily be excluded for candidacy from 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

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contraindication to kidney transplant unless specific criteria were present. These criteria are listed in this policy regarding HIV status and lung and lobar transplants. (*Refer to Policy Statement II C*).

According to the United Network for Organ Sharing (UNOS) 2023, wait times for transplants vary, and not everyone who needs a transplant will get one because of the shortage of organs that are suitable for donation. Only slightly more than 50% of people on the waiting list will receive an organ within five years. After the initial transplant evaluation, it is recommended that the awaiting transplant recipient work closely with their transplant team to remain an active recipient on a transplant waiting list.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- ***CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.***
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

CPT Codes

Code	Description
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

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HCPCS Codes

Code	Description
No code(s)	

ICD10 Codes

Code	Description
D38.1	Neoplasm of uncertain behavior of trachea, bronchus and lung
D81.810	Biotinidase deficiency
D84.1	Defects in the complement system
D86.0-D86.9	Sarcoidosis (code range)
E71.41	Primary carnitine deficiency

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Code	Description
E84.0-E84.9	Cystic fibrosis (code range)
I26.90	Septic pulmonary embolism without acute cor pulmonale
I26.99	Other pulmonary embolism without acute cor pulmonale
I27.00-I27.9	Other pulmonary heart diseases (code range)
J41.8	Mixed simple and mucopurulent chronic bronchitis
J43.0-J43.9	Emphysema (code range)
J44.9	Chronic obstructive pulmonary disease, unspecified
J47.9	Bronchiectasis, uncomplicated
J84.10-J84.114	Other interstitial pulmonary diseases with fibrosis (code range)
J84.2	Lymphoid interstitial pneumonia
J84.89	Other specified interstitial pulmonary diseases
J99	Respiratory disorders in diseases classified elsewhere
M32.13	Lung involvement in systemic lupus erythematosus
M33.01-M33.91	Dermatopolymyositis (code range)
M34.0-M34.9	Systemic sclerosis [scleroderma] (code range)
M35.02	Sicca syndrome with lung involvement
P27.0-P27.9	Chronic respiratory disease originating in the perinatal period (code range)
Q21.0	Ventricular septal defect
Q33.4	Congenital bronchiectasis
T80.0xxA	Air embolism following infusion, transfusion and therapeutic injection, initial encounter
T81.718A	Complication of other artery following a procedure, not elsewhere classified, initial encounter
T81.72xA	Complication of vein following a procedure, not elsewhere classified, initial encounter
T82.817A	Embolism of cardiac prosthetic devices, implants and grafts, initial encounter
T82.818A	Embolism of vascular prosthetic devices, implants and grafts, initial encounter

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*Key Article

KEY WORDS

Lobar Lung Transplant, Lung Transplant

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based on our review, Lung Transplant is not addressed in National or Regional Medicare coverage determinations or policies.