Medical Policy

Transplantation of Lung or Lobar Lung

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Product Applicability

- All Plan* Products

Well Sense Health Plan
- New Hampshire Medicaid
- NH Health Protection Program

Boston Medical Center HealthNet Plan
- MassHealth
- Qualified Health Plans/ConnectorCare/Employer Choice Direct
- Senior Care Options ◊

Notes:
+ Disclaimer and audit information is located at the end of this document.
◊ The guidelines included in this Plan policy are applicable to members enrolled in Senior Care Options only if there are no criteria established for the specified service in a Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) on the date of the prior authorization request. Review the member’s product-specific benefit documents at www.SeniorsGetMore.org to determine coverage guidelines for Senior Care Options.

Policy Summary

The Plan considers lung transplantation for end-stage pulmonary disease for adults and children to be medically necessary when applicable Plan medical criteria are met, including lobar lung transplant and lung transplantation (single-lung or double-lung replacement). All transplant-related consults, evaluations, procedures, and post-transplant follow-up services should be managed within the Plan’s provider network or at the most appropriate preferred transplant facility, depending upon the type of transplant. Prior authorization is required for all transplantation services. Heart-lung transplantation requires Plan Medical Director review.
It will be determined during the Plan’s prior authorization process if the specific transplant service is considered medically necessary for the requested indication within the Plan’s provider network, as appropriate. See Plan policy, *Medically Necessary* (policy number OCA 3.14), for the product-specific definitions of medically necessary treatment. When there is no Plan medical policy for the requested type of transplantation (e.g., simultaneous pancreas and lung transplantation), the Plan uses InterQual® criteria to determine medical necessity for the transplantation services, or the Plan conducts an individual evaluation of the member’s medical condition based on the Plan’s *Clinical Criteria* policy (policy number OCA 3.201) when InterQual® criteria are not established for the requested type of transplantation.

The Plan member must meet the eligibility criteria from the transplanting institution. The eligibility criteria of the transplanting institution must follow the applicable United Network for Organ Sharing (UNOS) guidelines. The hospital in which the organ transplants are performed must be a member of the Organ Procurement and Transplantation Network (OPTN) in accordance with the Public Health Service Act, comply with applicable OPTN organ allocation and procurement guidelines, and follow the Centers for Medicare & Medicaid Services (CMS) applicable conditions of participation for the specified organ to be transplanted (including but not limited to the following Code of Federal Regulations: 42 CFR Parts 405, 482, 488, and 498). The transplant program (including affiliated transplant facility, transplant surgeons, transplant physicians, and staff) must follow the designated UNOS/OPTN transplant program criteria for the applicable transplant service and comply with all applicable UNOS/OPTN professional standards. Senior Care Options members will have access to transplant services according all applicable CMS guidelines, including but not limited to the provisions specified in the Medicare Managed Care Manual, Chapter 4 – Benefits and Beneficiary Protections, 10.11 Transplant Services.

### Description of Item or Service

**Lung Transplantation:** The surgical replacement of lung from a deceased donor into a recipient. A lung transplant consists of replacing all or part of diseased lung(s) with healthy lung(s). A lung transplant refers to single-lung or double-lung replacement. In a single-lung transplant, only one (1) lung from a deceased donor is provided to the recipient. In a double-lung transplant, both of the recipient's lungs are removed and replaced by the donor's lungs.

**Lobar Lung Transplantation:** The surgical replacement of one (1) or both lungs in a recipient after removal of the right or left lower lung lobe from one (1) or two (2) donors (living donor or deceased donor). Lobar lung transplantation is usually reserved for pediatric patients who are not expected to survive the waiting time for a deceased donor transplant. 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 (1) lobe obtained from each of two (2) donors when bilateral transplantation is required. The living donor is left with four lung lobes, and the patient receives one of the donor’s lower lobes. When medically necessary, the recipient has both of the individual’s diseased lungs removed and receives two new lung lobes, one from each of two donors. There are also cases of cadaver lobe transplants.
Medical Policy Statement

Lobar lung (from one [1] or two [2] donors) or lung transplantation (single-lung or double-lung replacement) is considered medically necessary when the medical record documentation supports that the member, as assessed by the transplant surgeon or a designee of the multidisciplinary transplant team, meets ALL of the following applicable criteria for transplant clearance, as specified below in item A (Initial Transplantation and Retransplantation Criteria for Adult and Pediatric Members) and item B (Disease-Specific Criteria for Adult and Pediatric Members):

A. Initial Transplantation and Retransplantation Criteria for Adult and Pediatric Members:

See applicable criteria below, EITHER item 1 for criteria for an initial transplantation or item 2 for criteria for retransplantation.

1. Initial Transplantation Criteria:

   ALL of the following criteria must be met for an initial transplant for each adult member and pediatric member, as specified below in items a through m:

   a. Diagnosis of totally irreversible chronic pulmonary disease; AND

   b. Limited life expectancy of no more than two (2) years (based on the treating provider’s evaluation and clinical judgment); AND

   c. Oxygen dependence; AND

   d. Substantial limitation of daily activities; AND

   e. Evaluation demonstrating absence of potential complications that could diminish the success of transplantation; AND

   f. Acceptable nutritional status; AND

   g. Good rehabilitation potential; AND

   h. Compliance with medical management; AND

   i. Satisfactory psychosocial profile and emotional support system; AND

   j. Abstinence from smoking for at least six (6) months when history includes smoking; AND

   k. Pre-surgical clearance by a cardiologist for the transplantation; AND

   l. Pre-surgical clearance by a radiologist for the transplantation; AND

   m. Pre-surgical clearance by a surgeon for the transplantation; AND

   n. Pre-surgical clearance by an anesthesiologist for the transplantation; AND

   o. Pre-surgical clearance by a pharmacist for the transplantation; AND

   p. Pre-surgical clearance by a dentist for the transplantation; AND

   q. Pre-surgical clearance by a psychiatrist for the transplantation; AND

   r. Pre-surgical clearance by a psychologist for the transplantation; AND

   s. Pre-surgical clearance by a social worker for the transplantation; AND

   t. Pre-surgical clearance by a nutritionist for the transplantation; AND

   u. Pre-surgical clearance by an infectious disease specialist for the transplantation; AND

   v. Pre-surgical clearance by an infection control specialist for the transplantation; AND

   w. Pre-surgical clearance by an physiotherapist for the transplantation; AND

   x. Pre-surgical clearance by an occupational therapist for the transplantation; AND

   y. Pre-surgical clearance by a speech therapist for the transplantation; AND

   z. Pre-surgical clearance by a respiratory therapist for the transplantation; AND

   AA. Pre-surgical clearance by a pharmacist for the transplantation; AND

   BB. Pre-surgical clearance by a dentist for the transplantation; AND

   CC. Pre-surgical clearance by a psychiatrist for the transplantation; AND

   DD. Pre-surgical clearance by a psychologist for the transplantation; AND

   EE. Pre-surgical clearance by a social worker for the transplantation; AND

   FF. Pre-surgical clearance by a nutritionist for the transplantation; AND

   GG. Pre-surgical clearance by an infectious disease specialist for the transplantation; AND

   HH. Pre-surgical clearance by an infection control specialist for the transplantation; AND

   II. Pre-surgical clearance by a physiotherapist for the transplantation; AND

   JJ. Pre-surgical clearance by an occupational therapist for the transplantation; AND

   KK. Pre-surgical clearance by a speech therapist for the transplantation; AND

   LL. Pre-surgical clearance by a respiratory therapist for the transplantation; AND

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   OO. Pre-surgical clearance by a psychiatrist for the transplantation; AND

   PP. Pre-surgical clearance by a psychologist for the transplantation; AND

   QQ. Pre-surgical clearance by a social worker for the transplantation; AND

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   SS. Pre-surgical clearance by an infectious disease specialist for the transplantation; AND

   TT. Pre-surgical clearance by an infection control specialist for the transplantation; AND

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   NNN. Pre-surgical clearance by a psychologist for the transplantation; AND

   OOO. Pre-surgical clearance by a social worker for the transplantation; AND

   PPP. Pre-surgical clearance by a nutritionist for the transplantation; AND

   QQQ. Pre-surgical clearance by an infectious disease specialist for the transplantation; AND

   RRR. Pre-surgical clearance by an infection control specialist for the transplantation; AND

   SSS. Pre-surgical clearance by a physiotherapist for the transplantation; AND
I. All the transplanting institution’s eligibility criteria are met; AND

m. The transplant meets ONE (1) of the following criteria, as specified below as item (1) or item (2):

(1) A deceased donor will be used for the lung transplant (single-lung or double-lung replacement) or lobar lung transplant; OR

(2) A living donor will be used rather than a deceased donor for lobar lung transplantation when the transplant team has determined that the member is a suitable candidate for a living donor transplant and at least ONE (1) of the following criteria are met, as specified below as item (a), item (b), or item (c):

(a) A deceased donor is unavailable; OR

(b) Member is deteriorating clinically to the point of transplant ineligibility while waiting for deceased donor organ donation; OR

(c) Member is a critically ill child (since there is a shortage of suitable deceased donors for this age group); OR

2. Retransplantation Criteria:

Retransplantation is covered when BOTH of the following criteria are met, as specified below in item a and item b:

a. ALL criteria are met for the initial transplantation (as specified in item A1 above, Initial Transplantation Criteria); AND

b. The member has at least ONE (1) of the following indications, as specified below in item (1), item (2), or item (3):

(1) Graft failure of an initial lung or lobular lung transplant due to EITHER of the following, as specified below as item (a) or item (b):

(a) Technical reason, excluding serious reportable event and/or provider-preventable condition; OR

(Note: See Plan policy, Reimbursement Guidelines – Health Care Acquired Conditions, Provider Preventable Conditions and Serious Reportable Events, policy number 4.610 for BMC HealthNet Plan products and policy number WS

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4.29 for Well Sense Health Plan products, for definitions of serious reportable events and provider-preventable conditions)

(b) Hyperacute rejection (see Definitions section); OR

(2) Chronic rejection (see Definitions section); OR

(3) Recurrent disease; AND

B. Disease-Specific Criteria for Adult and Pediatric Members:

1. ALL applicable transplant criteria are met for EITHER an initial transplantation (as specified above in item A1) or retransplantation (as specified above in item A2); AND

2. The member has at least ONE (1) of the following diseases and ALL applicable criteria are met for that disease, as specified below in items a through e:

a. Bronchiectatic Disease:

Includes but is not limited to cystic fibrosis, acquired bronchiectasis, or congenital bronchiectasis with ALL of the following clinical indications, as specified below in items (1) through (4):

(1) Forced expiratory volume in 1 second (FEV1) ≤ 30% of predicted value or rapid respiratory deterioration with FEV1 >30%; AND

(2) paCO2 > 50 mm Hg; AND

(3) paO2 < 55 mm Hg; AND

(4) Increasing frequency and severity of exacerbations; OR

b. Nonbronchiectatic Disease:

Includes but is not limited to COPD, emphysema, alpha-1 antitrypsin disease, bronchiolitis obliterans syndrome (BOS), or chronic bronchitis with ALL of the following clinical indications, as specified below in items (1) through (5):

(1) FEV1 < 25% of the predicted value; AND

(2) paCO2 ≥ 55 mm Hg; AND
(3) \( \text{paO2} < 55-60 \text{ mm Hg}; \text{ AND} \)

(4) Elevated pulmonary artery pressures (secondary pulmonary hypertension); AND

(5) Clinical course - rapid rate of decline in FEV1 or life-threatening exacerbations; OR

c. **Interstitial Lung Disease:**

Includes but is not limited to idiopathic pulmonary fibrosis (IPF), interstitial pulmonary fibrosis, sarcoidosis, scleroderma, lymphangiomyomatosis, eosinophilic granuloma, pneumoconiosis or other lung disease due to external agents such as asbestos, crystalline silica, organic coal dust, or histiocytosis X with ALL of the following clinical indications, as specified below in items (1) through (5):

(1) Symptomatic, progressive disease with failure to respond to optimal medical treatment; AND

(2) Vital capacity < 60% to 65% of predicted value; AND

(3) Diffusing capacity of the lung for carbon monoxide (DLCO) < 50% to 60% of predicted value; AND

(4) Resting hypoxemia with \( \text{PaO2} < 55 \text{ mm Hg} \); AND

(5) Rapid progression of IPF warrants early referral; OR

d. **Pulmonary Hypertension:**

Includes but is not limited to primary or secondary due to cardiac disease, idiopathic pulmonary hypertension, pulmonary emboli, or Eisenmenger’s syndrome with ALL of the following clinical indications, as specified below in items (1) through (5):

(1) New York Heart Association functional class III or IV; AND

(2) Mean right atrial pressure of greater than 10 mm Hg; AND

(3) Mean pulmonary arterial pressure of greater than 50 mm Hg; AND

(4) Cardiac index of less than 2.5 L/min/m²; AND

(5) Failure of therapy with long-term prostacyclin infusion; OR

e. **Untreatable End-Stage Pulmonary Disease of Any Etiology**

Transplantation of Lung or Lobar Lung

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Limitations

1. Heart-Lung Transplantation:

   Plan Medical Director review is required for each prior authorization request for a heart-lung transplantation. For the Plan Medical Director to determine the medical necessity of the procedure, the treating provider must submit medical record documentation that supports the member’s diagnosis, past medical history (including previous medical, surgical, and pharmacological interventions and corresponding clinical outcomes), diagnostic test results, clinical indications for a heart-lung transplant, and documentation that the member has been assessed by the transplant surgeon or a designee of the multidisciplinary transplant and is considered an appropriate candidate for a heart-lung transplant, and documentation that the member has met the applicable criteria at the transplant center where the procedure is expected to be performed. Candidates for heart-lung transplantation are individuals with end-stage cardiopulmonary failure not amenable to conventional medical therapy or surgical repair; causes of end-stage cardiopulmonary failure may include irreparable congenital cardiac anomalies with pulmonary hypertension (Eisenmenger complex), primary pulmonary hypertension with irreversible right-heart failure, or sarcoidosis involving only the heart and lungs. The age of 60 years is the conventional upper limit for most candidates; however, transplant centers with more experience may evaluate patients older than 60 years on an individual basis.

2. The Plan considers ANY of the following services experimental and investigational, as specified below in items a through c:

   a. Lung transplantation for an individual with coronary artery disease not amenable to percutaneous intervention or bypass grafting, or an individual with coronary artery disease associated with significant impairment of left ventricular function is considered experimental and investigational.

   b. Lung xenotransplantation (e.g., porcine xenografts) is considered experimental and investigational for any indication.

   c. Prophylactic anti-reflux surgery to improve lung function and survival in lung transplant recipient without gastroesophageal reflux disease is considered experimental and investigational.

   See Plan policy, Experimental and Investigational Treatment (policy number OCA: 3.12), for the product-specific definitions of experimental or investigational treatment.
3. Contraindications to lung transplantation include but are not limited to ANY of the following, as specified below in item a. and/or item b:

a. **Absolute contraindications**, where there is no reasonable circumstance for undertaking transplant surgery, include at least ONE (1) of the following, as specified below in item 1 or item 2:

(1) Immunosuppressed or potentially exacerbated by immunosuppression with at least ONE (1) of the following conditions, as specified below in items (a) through (h):

(a) Known active malignancy, including metastatic cancer, other than non-melanomatous skin cancer; OR

(b) Recently treated malignancy within two (2) years of curative treatment without evidence of recurrence (within five [5] years for breast cancer, colorectal cancer, or melanoma); this absolute contraindication does NOT include an early stage cancer in which the cancerous growth or tumor is still confined to the site from which it started, and has not spread to surrounding tissue or other organs in the body (i.e., carcinoma in situ, cancer in situ, preinvasive carcinoma, in situ lesions); **OR**

(c) Malignancy with a moderate or high risk of recurrence; **OR**

** Note: The assessment of risk recurrence must be determined by the transplant team; the transplant team must then submit a written statement to the Plan explaining why the member with a recently treated malignancy or a member with a moderate or high risk of recurrence is an appropriate candidate for transplant surgery.

(d) AIDS (diagnosis based on CDC definition of CD4 count, 200cells/mm3) **unless** ALL of the following are noted in the member’s medical record, as specified below in items i through iv:

i. CD4 count >200cells/mm3 for more than 6 months; AND

ii. HIV-1 RNA undetectable; AND

iii. On stable anti-retroviral therapy more than 3 months; AND

iv. No other complications from AIDS (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidioido-mycosis, resistant fungal infections, Kaposi’s sarcoma or other neoplasm); OR
(e) Complicated or uncontrolled diabetes mellitus; OR

(f) Hepatitis B virus antigen positive (surface, core or both) based on criteria established by the transplantation center; OR

(g) Cirrhosis; OR

(h) Significant infection present outside the lungs and outside the upper respiratory tract; OR

(2) The member has at least ONE (1) of the following other conditions specified below in items (a) through (q):

(a) Active substance abuse or active smoking within the last six (6) months (including drug, alcohol, or tobacco); OR

(b) Inability to adhere to the therapeutic regimen necessary to preserve the transplant, including but not limited to compliance with the prescribed medication regimen, monitoring for signs and symptoms of complications, avoidance of risk factors that may result in adverse clinical outcomes, and/or attendance at regular clinical checkups; OR

(c) Acute or chronic infection that is not adequately treated; OR

(d) Active/symptomatic coronary artery disease with any ONE (1) of the following, as specified below in items i through iii:

   i. Not amendable to percutaneous intervention or bypass grafting; OR

   ii. Associated with significant impairment of left ventricular function; OR

   iii. Without cardiac clearance for transplantation; OR

(e) Active systemic collagen vascular (connective tissue) disease; OR

(f) Body mass index greater than 35 kg/m²; OR

(g) Cardiac insufficiency - right or left ventricular ejection fraction less than 20 percent; OR

(h) Demonstrated patient noncompliance which would place the organ at risk by not adhering to medical recommendations; OR

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(i) Non-rehabilitative pulmonary disability; OR

(j) Donor recipient incompatible as proven by positive cross match testing; OR

(k) Member lack of acceptance of potential complications from immunosuppressive medications; OR

(l) Significantly impaired hepatic function characterized by persistent and marked elevation of international normalized ratio (INR) or severe liver dysfunction caused by antituberculous therapy; OR

(m) Surgically remediable chronic thromboembolic disease; OR

(n) For a pediatric member (less than age 18 on the date of service), dysfunction of major organs other than the lung, particularly renal dysfunction with creatinine clearance of < 50, because of the impact of immunosuppressive drugs on renal function (and multiple-organ transplant may be considered as an alternative, when clinically appropriate); OR

(o) For an adult member (age 18 or older on date of service), extrapulmonary end-stage organ disease (and multiple-organ transplant may be considered as an alternative, when clinically appropriate); OR

(p) Active mycobacterium tuberculosis; OR

(q) Member is receiving high dose steroid therapy (more than 40 mg daily) that cannot be tapered or discontinued.

b. **Relative contraindications** are listed below items (1) through (8). Any ONE (1) of these contraindications puts the member at a higher risk of complications; this risk may be outweighed by other medical considerations and therefore transplant surgery may be considered after Medical Director review and approval if other Plan criteria are met:

1. Body mass index (BMI) less than 17 kg/m$^2$ or BMI 30 kg/m$^2$ or higher;† OR

‡ Note: This Plan policy also includes an absolute contraindication of BMI greater than 35 kg/m$^2$

2. Dependence on mechanical ventilation with clinically unstable pulmonary function tests; OR
(3) Age greater than 65 years old on the date of service for lobar lung transplant, single lung transplant, or double lung transplant; OR

(4) Significant chest wall or spinal deformity; OR

(5) Previous pleurodesis, pleurectomy, or complicated cardiothoracic surgery (excluding simple pneumothorax treated with closed tube thoracostomy, open lung biopsy, or uncomplicated lobectomy) which increases the technical difficulty of extracting the native lung and the operative risk of lung transplantation; OR

(6) Presence of significant esophageal dysfunction with ineffective esophageal motility that is likely to cause chronic rejection manifested as bronchiolitis obliterans syndrome, as determined by the treating provider or transplant surgeon; OR

(7) For a pediatric member (less than age 18 on the date of service), severe musculoskeletal disease affecting the thorax (e.g., kyphoscoliosis) and progressive neuromuscular disease

(8) Member with another medical condition that may cause end-organ damage (such as systemic hypertension, epilepsy, central venous obstruction, peptic ulcer disease, or gastroesophageal reflux) when the condition is not optimally treated before transplantation.

Definitions

Carcinoma In Situ: A group of abnormal cells that remain in the place where they first formed and have not spread. These abnormal cells may become cancer and spread into nearby normal tissue. Also called stage 0 disease.

Cardiac Index: A cardiodynamic measure based on the cardiac output, which is the amount of blood the left ventricle ejects into the systemic circulation in one minute, measured in liters per minute (l/min). Cardiac output is indexed to a patient's body size by dividing by the body surface area to yield the cardiac index.

Collagen Vascular Disease (CVD): A diverse group of autoimmune disorders (i.e., the body is allergic to itself) including: systemic lupus erythematosus, rheumatoid arthritis, progressive systemic sclerosis, dermatomyositis/polymyositis, ankylosing spondylitis, Sjögren syndrome, or mixed connective tissue diseases. Many CVDs involve the lungs either directly or as a complication of treatment of the CVD. Many parts of the respiratory system may be involved, including the airways, blood vessels, lung tissue, the tissue lining around the lungs and chest cavity, and/or respiratory muscles.
**Double Lung Transplant (Bilateral):** The surgical replacement of both lungs in the recipient by both lungs from a deceased donor. In general, this procedure may be appropriate for any ONE (1) of the following conditions, as specified below in items 1 through 3:

1. End-stage chronic obstructive pulmonary disease: Emphysema

2. Infectious lung disease:
   a. Bronchiectasis
   b. Cystic fibrosis

3. Pulmonary vascular disease:
   a. Eisenmenger’s syndrome with cardiac repair
   b. Primary pulmonary hypertension

**Lung Allocation Score (LAS):** The United Network for Organ Sharing (UNOS) has developed a system for prioritizing patients for lung transplants called the Lung Allocation Score System or LAS. The LAS system prioritizes lung transplant candidates age 12 and older for donor lung offers by assigning them a score from 0 to 100. The score is based on each patient’s individual medical information that reflects both the seriousness of each patient’s medical condition before transplant and the likelihood of success after a transplant; the score includes patient diagnosis, comorbidities, laboratory values, test results, and other clinical measures (including forced vital capacity, pulmonary artery and capillary wedge pressures, oxygen at rest, age, body mass index, functional status, six minute walk, serum creatinine, and if assisted ventilation is required). The candidate with the highest LAS in a particular age group will receive first priority for a donor lung offer.

**New York Heart Association (NYHA) Functional Class:** Functional classification system of heart failure that categorizes a patient’s condition and cardiovascular disability based on severity of symptoms and limitations during physical activity, as specified below in items 1 through 4:

1. NYHA Functional Class I (Mild): Patient with cardiac disease without limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, or dyspnea.

2. NYHA Functional Class II (Mild): Patient with cardiac disease with slight limitation of physical activity. Comfortable at rest, but ordinary physical activity results in fatigue, palpitation, or dyspnea.

3. NYHA Functional Class III (Moderate): Patient with cardiac disease producing marked limitation of physical activity. Comfortable at rest; less than ordinary physical activity causes fatigue, palpitation, dyspnea, or anginal pain.
4. NYHA Functional Class IV (Severe): Patient with cardiac disease resulting in inability to carry out any physical activity without discomfort. Symptoms of cardiac insufficiency or angina are present at rest; symptoms are increased with physical activity.

**Single Lung Transplant (Unilateral):** The surgical removal of a single lung from a deceased donor or living donor to replace one (1) lung in the recipient. In general, single lung transplantation may be appropriate for at least ONE (1) of the following conditions, as specified below in items 1 through 3:

1. Chronic obstructive pulmonary disease:
   Emphysema with or without alpha1-antitrypsin deficiency; OR
2. Interstitial lung disease:
   a. Eosinophilic granuloma; OR
   b. Idiopathic interstitial pulmonary fibrosis; OR
   c. Sarcoidosis; OR
   d. Lymphangioleiomyomatosis; OR
3. Pulmonary vascular disease:
   a. Eisenmenger's syndrome with cardiac repair; OR
   b. Primary pulmonary hypertension

**Transplant Rejection:** A process in which a transplant recipient's immune system attacks the transplanted organ or tissue. There are three (3) clinicopathologic stages of rejection:

1. Hyperacute Rejection: A recipient’s immune reaction that occurs within a few minutes after the transplant when the antigens are completely unmatched, resulting in organ failure within the first hours after transplantation. The tissue must be removed right away so the recipient does not die.

2. Acute Rejection: A recipient’s immune reaction that occurs any time from the first week after the transplant (during which the immune response increases in intensity) and generally up to 60 to 90 days after organ transplantation. It may be Grade I (mild), Grade II (moderate) or Grade III (severe). All recipients have some amount of acute rejection.
3. Chronic Rejection: A recipient’s immune reaction that occurs more than 60 days after transplantation and can take place over many years. This is the body’s constant immune response against the new organ that slowly damages the transplanted tissues or organ.

**Xenotransplantation:** According to the U.S. Public Health Service, xenotransplantation is defined as any procedure that involves the transplantation, implantation, or infusion into a human recipient of either of the following, as specified below in item 1 or item 2:

1. Live cells, tissues, or organs from a non-human animal source; OR

2. Human body fluids, cells, tissues or organs that have had ex vivo contact with live non-human animal cells, tissues, or organs. (See this policy’s Limitations section.)

**Applicable Coding**

The Plan uses and adopts up-to-date Current Procedural Terminology (CPT) codes from the American Medical Association (AMA), International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) diagnosis codes developed by the World Health Organization and adapted in the United States by the National Center for Health Statistics (NCHS) of the Centers for Disease Control under the U.S. Department of Health and Human Services, and the Health Care Common Procedure Coding System (HCPCS) established and maintained by the Centers for Medicare & Medicaid Services (CMS). Because the AMA, NCHS, and CMS may update codes more frequently or at different intervals than Plan policy updates, the list of applicable codes included in this Plan policy is for informational purposes only, may not be all inclusive, and is subject to change without prior notification. Whether a code is listed in the Applicable Coding section of this Plan policy does not constitute or imply member coverage or provider reimbursement. Providers are responsible for reporting all services using the most up-to-date industry-standard procedure and diagnosis codes as published by the AMA, NCHS, and CMS at the time of the service.

Providers are responsible for obtaining prior authorization for the services specified in the Medical Policy Statement section and Limitation section of this Plan policy, even if an applicable code appropriately describing the service that is the subject of this Plan policy is not included in the Applicable Coding section of this Plan policy. Coverage for services is subject to benefit eligibility under the member’s benefit plan. Please refer to the member’s benefits document in effect at the time of the service to determine coverage or non-coverage as it applies to an individual member. See Plan reimbursement policies for Plan billing guidelines.

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<tr>
<th>CPT Codes</th>
<th>Description: Codes Covered When Medically Necessary</th>
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<tbody>
<tr>
<td>32851</td>
<td>Lung transplant, single; without cardiopulmonary bypass</td>
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<tr>
<td>32852</td>
<td>Lung transplant, single; with cardiopulmonary bypass</td>
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<tr>
<td>32853</td>
<td>Lung transplant, double (bilateral sequential or en bloc); without cardiopulmonary bypass</td>
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Clinical Background Information

Lung transplantation may be appropriate for patients with advanced lung disease whose clinical status has progressively declined despite maximal medical or surgical therapy with a limited life expectancy over the next two (2) years. Candidates are usually symptomatic during activities of daily living and ideally should be free of any other organ dysfunction or medical problem that would substantially jeopardize the outcome of transplantation. (Source: Hachem RR. UpToDate®). Lung transplantation has become a viable treatment option for selected patients with end-stage lung disease due to a wide variety of underlying disorders. Single, double, and lobar-lung transplantation have all been performed successfully. The type of lung transplantation procedure used (i.e., lobar, single, or double) and donor type (i.e., deceased or living) are based upon the candidate’s condition and indication for transplantation, and the availability of donor organs. As donor organs are scarce relative to the number of candidates needing transplantation, conservation of acceptable donor organs is also taken into consideration. Deceased donor lung transplantation, also known as cadaveric donor lung transplantation, is most commonly performed. Individuals older than age 12 are allocated donated deceased donor lungs using the Lung Allocation Score based on survival benefit and medical condition. Organ allocation to children under age 12 is based solely on waiting time.

Living donor lobar lung transplantation has shown success and addresses the shortage of deceased donor organs. Living donor lobar lung transplantation is less commonly performed. A transplant from living donors usually involves three operations, one on each of two donors and one on the recipient. The lower lobe of the right lung is removed from one donor and the lower lobe of the left lung is removed from the other donor. Both lungs are then removed from the recipient and are replaced by the lung implants from the donors in a single operation. Although deceased donor lung transplantation is preferred to avoid risk to two healthy donors, living donor lobar lung transplant may be an acceptable alternative when the recipient (usually a child or adolescent) is not likely to survive long enough to receive deceased donor lungs.

The goal of lung transplantation is to improve quality of life and long-term survival in patients with end-stage pulmonary disease. Advances in donor and recipient selection, new immunosuppressive medications, new and improved surgical techniques, and increased medical management of infections

Transplantation of Lung or Lobar Lung

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have improved the overall survival in patients after lung transplantation. Consideration for lung transplantation is based on an evaluation for potential complications that could diminish its success.

Lung transplantation is an effective treatment for end stage lung disease. However, long-term survival is limited by the development of chronic rejection manifested as bronchiolitis obliterans syndrome (BOS). GER and altered motility has long been associated with lung disease and are common among patients and the post lung transplant population. The evidence collected to date strongly supports a role for the aspiration of gastric contents as a causative or additive etiology to developing BOS. Common in advanced lung disease, changes in diaphragmatic position, decreased lower esophageal sphincter pressure, and changes in intrathoracic pressure are proposed mechanisms favoring reflux. Ineffective esophageal motility (IEM) is the most common motility disorder in patients with GER-associated respiratory symptoms. Aspiration secondary to GER and altered foregut motility have been identified as potential contributors to lung allograft dysfunction. Lung transplant recipients appear to be at increased risk of GER and aspiration through the following mechanisms: (1) The cough reflexes and mucociliary clearance which are the normal defense mechanisms against aspiration are dramatically impaired; (2) mucociliary clearance is less than normal in transplanted lungs (measured to be less than 15% of normal); and (3) It is hypothesized that even small amounts of aspiration can lead to significant injury, particularly with multiple repeated episodes over time (with a causative or additive etiology to develop BOS).

The U.S. Department of Health and Human Services (DHHS) has oversight responsibility for the organ allocation system in the United States. Congress established the Organ Procurement and Transplantation Network (OPTN) when it enacted the National Organ Transplant Act (NOTA) of 1984. The Act called for a unified transplant network to be operated by a private, nonprofit organization under federal contract. United Network for Organ Sharing (UNOS) was awarded the initial OPTN contract in 1986 and continues to administer the OPTN.

At the time of the Plan’s most recent policy review, no national coverage determination (NCD) or local coverage determination (LCD) was found from the Centers for Medicare & Medicaid Services (CMS) for single, double, and/or lobar lung transplantation. CMS requires that services be performed at a Medicare-approved facility for lung transplant services (as specified in 42 CFR Parts 405, 482, 488, and 498 Medicare Program, Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers to Perform Organ Transplants, Final Rule, March 30, 2007). CMS evaluates detailed criteria for facility participation that include but are not limited to the following: Clinical experience, patient selection of suitable candidates, patient management with good patient outcomes, experience and survival rates, maintenance of data, organ procurement, laboratory services, and billing guidelines. Senior Care Options members will have access to transplant services according all applicable CMS guidelines, including but not limited to the provisions specified in the Medicare Managed Care Manual, Chapter 4 – Benefits and Beneficiary Protections, 10.11 Transplant Services. Verify applicable CMS criteria are in effect for lung transplant services in an NCD or LCD on the date of the prior authorization request for a Senior Care Options member.
References


Benditt JO. Surgical options for patients with COPD: sorting out the choices. Respir Care. 2006 Feb;51(2): 173-82.


Transplantation of Lung or Lobar Lung

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Kilic A, Merlo CA, Conte JV, Shah AS. Lung transplantation in patients 70 years old or older: have outcomes changed after implementation of the lung allocation score? J Thorac Cardiovasc Surg 2012; 144:1133.


MediLexicon International Ltd. Definition: New York Heart Association Classification. Source: Stedman’s Medical Dictionary, 2006; Lippincott Williams & Wilkins.


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United Network for Organ Sharing (UNOS). Questions and Answers for Transplant Professionals about Lung Allocation.


Transplantation of Lung or Lobar Lung

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<table>
<thead>
<tr>
<th>Original Approval Date</th>
<th>Original Effective Date* and Version Number</th>
<th>Policy Owner</th>
<th>Original Policy Approved by</th>
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<tbody>
<tr>
<td>Regulatory Approval: N/A</td>
<td>10/02/05 Version 1</td>
<td>Medical Policy Manager as Chair of Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC)</td>
<td>Quality and Clinical Management Committee (Q&amp;CMC)</td>
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<td>Internal Approval: 08/02/05</td>
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*Effective Date for the BMC HealthNet Plan Commercial Product(s): 01/01/12
*Effective Date of the Well Sense Health Plan New Hampshire Medicaid Product(s): 01/01/13
*Effective Date for Senior Care Options Product(s): 01/01/16

Policy formerly titled Lung Transplant until 07/31/13.

<table>
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<tr>
<th>Review Date</th>
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<th>Revision Effective Date and Version Number</th>
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<tr>
<td>02/06/07</td>
<td>Updated template and references.</td>
<td>Version 2</td>
<td>02/06/07: Q&amp;CMC</td>
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<td>02/19/08</td>
<td>Revised clinical criteria.</td>
<td>Version 3</td>
<td>02/19/08: MPCTAC 02/26/08: Utilization Management Committee (UMC) 03/12/08: QIC</td>
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<tr>
<td>02/24/09</td>
<td>Updated clinical criteria for HIV. Updated coding and references.</td>
<td>Version 4</td>
<td>02/24/09: MPCTAC 02/24/09: UMC 03/25/09: QIC</td>
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<tr>
<td>02/01/10</td>
<td>Updated references.</td>
<td>Version 5</td>
<td>02/22/10: MPCTAC 03/24/10: QIC</td>
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<tr>
<td>03/01/11</td>
<td>Updated references. Updated the clinical guideline statement and the medically appropriate indications with</td>
<td>Version 6</td>
<td>03/16/11: MPCTAC 04/27/11: QIC</td>
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## Policy Revisions History

<table>
<thead>
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<th>Date</th>
<th>Description</th>
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<tr>
<td>03/12/12</td>
<td>Updated references and clinical guideline statement. Updated and clarified contraindications.</td>
<td>Version 7</td>
<td>03/21/12: MPCTAC 04/25/12: QIC</td>
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<tr>
<td>08/01/12</td>
<td>Off cycle review for Well Sense Health Plan. Reformatted Medical Policy Statement, revised Applicable Coding introduction, updated code list, and revised Limitations section.</td>
<td>Version 8</td>
<td>08/13/12: MPCTAC 09/06/12: QIC</td>
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<tr>
<td>04/01/13</td>
<td>Review for effective date 08/01/13. Revised title, removed redundant text in Clinical Background Information section, revised Summary and Description of Item or Service sections, added clinical criteria and limitations, revised and added definitions, updated language in Applicable Coding section and revised applicable code list, added text to Clinical Background Information section, and added and updated references. Referenced <em>Medically Necessary</em> policy, <em>Experimental and Investigational Treatment</em> policy, and <em>Reimbursement Guidelines: Serious Reportable Event/Provider Preventable Condition</em>.</td>
<td>Version 9</td>
<td>04/17/13: MPCTAC 05/16/13: QIC</td>
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<tr>
<td>03/01/14</td>
<td>Review for effective date 07/01/14. Updated Summary and References sections. Revised criteria in the Medical Policy Statement section and the Limitations section.</td>
<td>Version 10</td>
<td>07/01/14: MPCTAC 04/16/14: QIC</td>
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<td>03/01/15</td>
<td>Review for effective 05/01/15. Updated Summary and References sections. Removed Commonwealth Care, Commonwealth Choice, and Employer Choice from the list of applicable products because the products are no longer available.</td>
<td>Version 11</td>
<td>05/01/15: MPCTAC 04/08/15: QIC</td>
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<td>03/01/16</td>
<td>Review for effective date 07/01/16. Updated Summary, Definitions, Clinical Background Information, References, and References to Applicable Laws and Regulations sections. Administrative changes made to the Medical Policy Statement section. Revised criteria in the Limitations section.</td>
<td>07/01/16</td>
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<td>Review for effective date 06/07/17. Updated Summary, Definitions, Clinical Background Information, and References sections. Revised criteria in the Medical Policy Statement and Limitations sections. Plan notes added to the Applicable Coding section.</td>
<td>06/07/17</td>
<td>Version 14</td>
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## Last Review Date

03/01/17

## Next Review Date

03/01/18

## Authorizing Entity

MPCTAC

## Other Applicable Policies

- Administrative Policy - *Clinical Criteria*, policy number OCA 3.201
- Administrative Policy - *Transplantation Administration*, policy number OCA 3.10
- Medical Policy - *Experimental and Investigational Treatment*, policy number OCA 3.12
- Medical Policy - *Medically Necessary*, policy number OCA 3.14
- Medical Policy - *Transplantation of Pancreas or Pancreas-Kidney*, policy number OCA 3.25
- Medical Policy - *Transplantation of Small Bowel, Small Bowel-Liver, or Multivisceral Organs*, policy number OCA 3.26
- Reimbursement Policy - *Anesthesia*, policy number 4.103
- Reimbursement Policy - *General Billing and Coding Guidelines*, policy number 4.31
- Reimbursement Policy - *General Clinical Editing and Payment Accuracy Review Guidelines*, policy number 4.108

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Reimbursement Policy - *Inpatient Hospital*, policy number 4.110
Reimbursement Policy - *Outpatient Hospital*, policy number 4.17
Reimbursement Policy - *Physician and Non Physician Practitioner Services*, policy number 4.608

**Reference to Applicable Laws and Regulations**


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**Disclaimer Information:**

Medical Policies are the Plan’s guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member’s benefit document, and when appropriate, coordinates with the Member’s health care Providers to consider the individual Member’s health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan’s service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member’s benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.