

BENEFIT COVERAGE POLICY

Title: BCP-70 Lung Transplantation

Effective Date: 07/01/2021



Physicians Health Plan
PHP Insurance Company
PHP Service Company

Important Information - Please Read Before Using This Policy

The following coverage policy applies to health benefit plans administered by PHP and may not be covered by all PHP plans. Please refer to the member's benefit document for specific coverage information. If there is a difference between this general information and the member's benefit document, the member's benefit document will be used to determine coverage. For example, a member's benefit document may contain a specific exclusion related to a topic addressed in a coverage policy.

Coverage determinations for individual requests require consideration of:

- The terms of the applicable benefit document in effect on the date of service.
- Any applicable laws and regulations.
- Any relevant collateral source materials including coverage policies.
- The specific facts of the particular situation.

Contact PHP Customer Service to discuss plan benefits more specifically.

1.0 Policy:

Lung transplant may be considered medically necessary for patients with irreversible, progressively disabling, primary or secondary end-stage lung disease. Prior to consideration for transplant, patients should be receiving maximal medical therapy including oxygen supplementation or surgical options such as lung-volume reduction surgery for COPD. See Sec. 3.0.B Qualifying Conditions. The Health Plan covers lung transplant for members with a qualifying condition and who meet the clinical determination guidelines below.

All transplant related services require prior approval for coverage of Covered Health Services provided at a Health Plan designated transplant facility. Contact the Transplant Case Manager to verify if a provider is contracted as a designated transplant facility.

There is no benefit coverage for non-network transplant services (see section 5.0 for exceptions).

Lung transplants can only be done in an inpatient setting.

Refer to member's benefit coverage document for specific benefit description, guidelines, coverage, and exclusions.

2.0 Background:

Lung transplantation has become a viable treatment option for carefully selected patients with end-stage pulmonary disease. Single, double, and lobar-lung transplantation have all been performed successfully for a variety of diseases. Single lung transplantation appears to be most effective for patients with end-stage pulmonary fibrosis, while double lung transplantation is most effective for patients with end-stage chronic obstructive pulmonary disease (COPD) and cystic fibrosis (CF) in whom cardiac function has been preserved. Lobar lung transplantation (from living donors or cadaver donors) is usually reserved for children or adolescents who are appropriate candidates and will not survive waiting for cadaver lungs. Indications for lung transplantation in pediatric patients include pulmonary vascular disease, bronchiolitis obliterans, broncho-pulmonary dysplasia, graft failure due to viral pneumonitis, and CF.

Chronic obstructive pulmonary disease and alpha 1-antitrypsin deficiency, the 2 principal causes of emphysema, are responsible for approximately 60 % of all single lung transplants performed. Other indications for single lung transplantation include primary pulmonary hypertension, Eisenmenger's syndrome, as well as a variety of interstitial lung diseases (e.g., interstitial pulmonary fibrosis).

Cystic fibrosis, emphysema, and alpha 1-antitrypsin deficiency are the most common indications for double lung transplantation, also known as bilateral single lung transplantation (sequential replacement of both lungs).

Although lung transplantation offers acceptable prospects for five-year survival, chronic rejection and donor shortage remain to be a major problem. To address the problem of donor shortage, living-donor lobar lung transplantation has been performed with satisfactory intermediate survival and functional results. In lobar lung transplantation, a lobe of the donor's lung is excised, sized appropriately for the recipient, and transplanted. Common indications for living-donor bilateral lobar lung transplantation are CF and severe primary pulmonary hypertension. Based on available scientific evidence, there is no significant difference in effectiveness between living-donor lobar lung transplantation and cadaver lobar lung transplantation.

3.0 Clinical Determination Guidelines:

- A. Lung transplantation is considered medically necessary and appropriate when all the following are met:
1. Documentation of compliance with medical management; AND
 2. Member should have received prior authorization for pre-transplant services (evaluation, outpatient diagnostics and labs) at a Health Plan designated transplant facility linked to one of the transplant networks: *Interlink*, *LifeTrac* or *Cigna LifeSource*. If a member is not receiving services at a Health Plan designated facility, the member will need to be redirected to a designated facility; AND
 3. Social work evaluation indicating member does not have any unresolvable psychosocial problems which may interfere with compliance with transplant management; AND
 4. Member has completed an evaluation and has been accepted by the transplant committee at a designated transplant facility. Documentation must include a summary letter from the transplant center indicating acceptance and outlining the preoperative tests and their results; AND
 5. The member meets the transplanting facility's selection criteria (this includes meeting United Network for Organ Sharing [UNOS] guidelines for a lung allocation score greater than zero); AND
 6. Attending physician has determined there are no prohibitive risk factors or absolute contraindications for transplant recipients, all of the following criteria must be met and none of the contraindications should be present:
 - a. Adequate liver and kidney function defined as a bilirubin of less than 2.5 mg/dl and a creatinine clearance of greater than 50 ml/min/kg; AND
 - b. Adequate cardiac status defined as no angiographic evidence of significant coronary artery disease, ejection fraction greater than 40%, no myocardial infarction in the last six months, and a negative stress test; AND
 - c. Adequate functional status. Under established guidelines, active rehabilitation is considered important to the success of transplantation. Mechanically ventilated or otherwise immobile persons are considered poor candidates for transplantation; AND
 - d. Absence of acute or chronic active infection (pulmonary or non-pulmonary) that is not adequately treated; AND
 - e. Limited life expectancy of less than two years; AND

- f. No uncontrolled and/or untreated psychiatric disorders that interfere with compliance to a strict treatment regimen; AND
- g. Members with a history of using alcohol, tobacco and other substances of abuse must be abstinent for a minimum of six consecutive months before being considered an eligible transplant candidate. This is determined by random urine drug screens with negative results. Use of marijuana for medical purposes requires written approval from the referring specialist (cardiologist, pulmonologist, nephrologist, etc.) and transplant eligibility is subject to the transplanting institution's criteria; AND
- h. Absence of inadequately controlled HIV/AIDS infection, defined as:
 - i. CD4 count greater than 200 cells/mm³ for greater than six months; and
 - ii. Undetectable HIV viremia (<50 HIV-1 RNA copies/ml) for at least six months; and
 - iii. Demonstrates adherence and a stable, highly active antiretroviral therapy regimen for at least six months; and
 - iv. Absence of AIDS-defining illness following successful immune reconstitution after highly active antiretroviral therapy.

B. Qualifying conditions (not an all-inclusive list):

- 1. Alpha 1-antitrypsin deficiency - persons who meet the emphysema/alpha 1-antitrypsin deficiency disease specific selection criteria below.
- 2. Broncho-pulmonary dysplasia.
- 3. Congenital heart disease (Eisenmenger's defect or complex) - persons who meet the Eisenmenger's disease-specific criteria below.
- 4. Cystic fibrosis – persons who meet the cystic fibrosis disease specific criteria below.
- 5. Graft-versus-host disease or failed primary lung graft.
- 6. Lymphagioliomyomatosis (LAM) with end-stage pulmonary disease.
- 7. Obstructive lung disease (e.g., emphysema, chronic obstructive pulmonary disease, bronchiolitis obliterans, bronchiectasis). For persons with pulmonary fibrosis, see the disease specific selection criteria below.
- 8. Primary pulmonary hypertension (PPH) – persons who meet the PPH disease-specific criteria below.
- 9. Restrictive lung disease (e.g., idiopathic pulmonary fibrosis, desquamative interstitial fibrosis, post-chemotherapy, allergic alveolitis, system sclerosis [scleroderma], collagen vascular disease, asbestosis, eosinophilic granuloma, and sarcoidosis). For persons with sarcoidosis, see the disease specific selection criteria below.

C. Disease-specific selection criteria:

- 1. Lung transplantation for *emphysema*, including *alpha 1-antitrypsin deficiency*, is considered medically necessary for persons who meet the general criteria for lung transplantation and both of the following criteria:
 - a. Hospitalizations for exacerbation of COPD associated with hypercapnia in the preceding year. Hypercapnia is defined as pCO₂ greater than or equal to 50 mm HG with hospitalizations and/or the following associated factors:
 - i. Reduced serum albumin.
 - ii. Declining body mass index.
 - iii. Increasing oxygen requirements.

- iv. Presence of cor pulmonale, defined as a clinical diagnosis by a physician or any two of the following:
 - 1) Right ventricular hypertrophy or right atrial enlargement of EKG.
 - 2) Enlarged pulmonary arteries on chest x-ray.
 - 3) Pedal edema or jugular venous distention.
 - 4) Mean pulmonary artery pressure by right heart catheterization of greater than 25 mm Hg at rest or 30 mm Hg with exercise.
- b. BODE index of seven or above (indicating two years or less survival).
2. Lung transplantation for Eisenmenger's complex is considered medically necessary for persons who meet the general criteria for lung transplantation and **any** of the following criteria:
 - a. Signs of right ventricular failure (e.g. progressive hepatomegaly, ascites).
 - b. Marked deterioration in functional capacity (NYHA Class III).
 - c. Pulmonary hypertension with a mean pulmonary artery pressure (PAP) by right heart catheterization greater than 25 mm Hg at rest or 30 mm Hg with exercise.
3. Lung transplantation for cystic fibrosis is considered medically necessary for persons who meet the general selection criteria for lung transplantation and exhibit **at least two** of the following signs and symptoms of clinical deterioration:
 - a. Initiation of supplemental enteral feeding by percutaneous endoscopic gastrostomy or parenteral nutrition.
 - b. Cycling intravenous antibiotic therapy.
 - c. Non-invasive nocturnal mechanical ventilation.
 - d. Increasing frequency of hospital admissions.
 - e. Increasingly severe exacerbations of cystic fibrosis, especially an episode require hospital admission.
 - f. Recurrent massive hemoptysis.
 - g. Development of CO₂ retention (pCO₂ greater than 50 mm Hg).
 - h. Worsening arterial-alveolar (A-a) gradient requiring increasing concentrations of inspired oxygen.
 - i. Decreasing forced expiratory volume in one second (FEV₁).
 - j. FEV₁ less than 30% of predicted.
 - k. Recurrent pneumothorax.
4. Lung transplantation for pulmonary fibrosis is considered medically necessary for persons who meet the general criteria for lung transplantation and **any** of the following disease-specific criteria:
 - a. Presence of cor pulmonale (indicative of severe pulmonary fibrosis) or pulmonary hypertension.
 - b. Diffusing capacity for carbon monoxide (DLCO) less than 60% of predicted.
 - c. Total lung capacity (TLC) less than 70% of predicted.
5. Lung transplantation for pulmonary hypertension is considered medically necessary for persons who meet the general criteria for lung transplantation, plus of the following criteria and hemodynamically significant valvular disease has been excluded by echocardiography:

- a. Persons who are NYHA III and failing conventional vasodilators.
 - b. Persons who are NYHA III and have initiated or are being considered for initiation of parenteral or subcutaneous vasodilator therapy.
- Note: NYHA III - See Table 2. below under Terms & Definitions.
- c. Pulmonary hypertension with mean pulmonary artery pressure by right heart catheterization of greater than 25 mm Hg at rest or 30 mm Hg with exercise, or pulmonary artery systolic pressure of 50 mm Hg or more defined by echocardiography or pulmonary angiography.
6. Lung transplant for sarcoidosis is considered medically necessary for persons who meet the general criteria for lung transplantation plus **any** of the following disease specific criteria:
- a. Presence of cor pulmonale (indicative of severe pulmonary fibrosis) or pulmonary hypertension.
 - b. Total lung capacity less than 70% predicted.
 - c. Diffusion capacity (DLCO) less than 60% of predicted.
- D. Contraindications (potential contraindications are subject to the judgment of the transplant center):
1. Lung transplantation is considered experimental and investigational for persons with the following contraindications as the safety and effectiveness has not been established when:
 - a. Multi-system disease. Persons with potential multi-system diseases such as systemic sclerosis (scleroderma), other collagen vascular diseases such as system lupus erythematosus, or sarcoidosis must be carefully evaluated to ensure their disease is primarily confined to the lung. Persons with diabetes must be carefully evaluated to rule out significant diabetic complications such as nephropathy, neuropathy or retinopathy.
 - b. Untreated systemic infection making immunosuppression unsafe, including chronic infection.
 - c. Stable systemic disease that could be exacerbated by immunosuppression.
 - d. Smoking. Persons with a history of smoking (tobacco or other substances of abuse) must be abstinent for a minimum of six consecutive months as determined by negative random, urine drug screens to be considered eligible for lung transplantation.
 - e. Malignancy involving the lung (primary or metastatic). Persons with a history of non-pulmonary cancer must be in remission before being considered a lung transplant candidate. Note: Because of disappointing results, lung transplantation is considered experimental and investigation as a treatment for bronchio-alveolar carcinoma.
 - f. Presence of gastrointestinal disease (e.g. bleeding peptic ulcer, diverticulitis, chronic hepatitis).
 - g. Psychosocial conditions or chemical dependency affecting a person's ability to adhere to post-transplant therapy.
 - h. Refractory uncontrolled hypertension.
 - i. Other effective medical treatments or surgical options are available.
 - j. Single lung transplantation is contraindicated in persons with chronic pulmonary infections (e.g., bronchiectasis, chronic bronchitis, and cystic fibrosis).
- E. Lobar Lung Transplantation from living-related donors or cadaver donors is medically necessary for persons with end stage pulmonary disease when selection criteria are met (see above criteria).
- F. The following are not covered as they are considered experimental/investigational and effectiveness has not been established:

1. TransMedics Organ Care System for the preservation and transport of donor lungs. There is no specific code for this service.
2. Lung xenotransplantation (e.g., porcine xenografts) for any pulmonary condition (CPT 32999).

4.0 Coding:

Prior Approval Legend: Y = All lines of business; N = None required; 1 = HMO/POS; 2 = PPO; 3 = ASO group L0000264; 4 = ASO group L0001269 Non-Union & Union; 5 = ASO group L0001631; 6 = ASO group L0002011; 7 = ASO group L0001269 Union Only; 8 = ASO group L0002184.

| COVERED CODES | | | |
|----------------------|-------------------------------------------------------------------------------------------|-----------------------|------------------------------------------|
| Code | Description | Prior Approval | Benefit Plan Cost Share Reference |
| 32850 | Donor pneumonectomy(s) (including cold preservation), from cadaver donor | Y | Transplantation Services |
| 32851 | Lung transplant, single without cardiopulmonary bypass | Y | Transplantation Services |
| 32852 | Lung transplant, single; with cardiopulmonary bypass | Y | Transplantation Services |
| 32853 | Lung transplant, double (bilateral sequential or en bloc); without cardiopulmonary bypass | Y | Transplantation Services |
| 32854 | Lung transplant, double (bilateral sequential or en bloc); with cardiopulmonary bypass | Y | Transplantation Services |
| S2060 | Lobar lung transplantation | Y | Transplantation Services |
| S2061 | Donor lobectomy (lung) for transplantation, living donor | Y | Transplantation Services |

5.0 Unique Configuration/Prior Approval/Coverage Details:

Fully-insured SPD plans and self-funded group L0001631 plans have a Travel and Lodging Benefit included in the transplant benefit (see benefit documents for details).

6.0 Terms & Definitions:

Active candidate – A candidate on the waiting list who is currently suitable for transplantation and eligible to receive organ offers.

Allograft – The transplant of an organ or tissue from one individual to another. Also called allogeneic or homograft.

BODE Index – (Body mass index (BMI), airflow Obstruction, Dyspnea, and Exercise (is a multi-dimensional capacity index for COPD.)) The index uses four factors for predicting the risk of death from the disease: FEV1, BMI, dyspnea score and 6-minute walk test.

An online tool for calculating the BODE Index is available at the following website:

<http://reference.medscape.com/calculator/bode-index-copd>.

Cadaveric (deceased) donor – An individual from whom an organ is recovered for transplant after declaration of death.

Designated facility – A facility that has entered into an agreement on behalf of the facility and its affiliated staff with us or with an organization contracting on our behalf, to render covered health services for the treatment of specified diseases or conditions. A designated facility may or may not be located within your geographic area. The fact that a hospital is a network hospital does not mean that it is a designated facility.

Graft failure – A significant complication following an allogeneic transplant in which a transplanted organ or tissue loses function. Graft failure statistics are recorded at one month, one year and three years' post-transplant.

Graft rejection – A process in which the immune system of the transplant recipient attacks the transplanted organ or tissue. Graft rejection is the major cause of graft failure. There are three types of rejection:

- Hyperacute rejection – usually occurs within the first 24 hours of transplantation with a high risk of rapid clumping of red blood cells.
- Acute rejection – usually begins after the first week of transplantation with the risk at its highest in the first 3 months after transplantation. Occurs in approximately 10-20% of kidney transplants.

Chronic rejection – Occurs months to years following transplantation with risk factors identified such as young recipient age, Afro-American race, pre-sensitization (pregnancies, blood transfusions or failed transplants), and acute rejection episodes.

Inactive candidate – A candidate who is temporarily unavailable or unsuitable for transplantation, and appears as inactive on the waiting list.

Living donor lobar lung transplantation – Right or left lower lung lobe is removed from one or two living adult donors and transplanted into an adult or pediatric recipient.

Lung Allocation Score (LAS) – Used to prioritize wait listed candidates based on a combination of waitlist urgency and post-transplant survival.

LAS Calculator available at: <https://optn.transplant.hrsa.gov/resources/allocation-calculators/las-calculator/>.

Table 1. LAS Primary Diagnostic Groupings for Lung Transplant Candidates

| LAS Lung Disease Diagnostic Grouping | Diagnoses |
|---------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Group A (obstructive lung disease) | COPD w/ or w/o Alpha 1 Antitrypsin Disease due to chronic bronchitis and/or emphysema LAM Bronchiectasis, including primary ciliary dyskinesia Sarcoidosis w/ a mean PAP ≤ 30 mm Hg |
| Group B (pulmonary vascular disease) | Idiopathic pulmonary hypertension (iPH; formerly known as primary pulmonary hypertension) Eisenmenger's syndrome Other pulmonary vascular diseases |
| Group C (CF or immunodeficiency disorders) | CF Immunodeficiency disorders such as hypogammaglobulinemia |
| Group D (restrictive lung disease) | Idiopathic pulmonary fibrosis Pulmonary fibrosis due to other causes Sarcoidosis w/ a mean PAP > 30 mm Hg Obliterative bronchiolitis (non-retransplant) |

New York Heart Association (NYHA) classification – One of the many parameters used for selecting heart recipients. It is a 4-tier system that categorizes patients based on subjective impression of the degree of functional compromise.

Table 2. NYHA Classification of Cardiac Patients

| Functional Classification of Cardiac Patients | Physiologic Symptoms |
|------------------------------------------------------|-----------------------------|
|------------------------------------------------------|-----------------------------|

| Functional Classification of Cardiac Patients | Physiologic Symptoms |
|-----------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| I (Mild) | No limitation of physical activity: ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain. |
| II (Mild) | Slight limitation of physical activity: comfortable at rest; ordinary physical activity results in fatigue, palpitation, dyspnea, or anginal pain. |
| III (Moderate) | Marked limitation of physical activity: comfortable at rest; less than ordinary physical activity causes fatigue, palpitation, dyspnea, or anginal pain. |
| IV (Severe) | Inability to carry on any physical activity without discomfort; symptoms of cardiac insufficiency or of the anginal syndrome may be present even at rest; if any physical activity is undertaken, discomfort increases. |

6-minute walk distance – A measure of functional status, the distance you can walk in 6 minutes.

National Organ Transplant Act (NOTA) – Act passed by the Congress of the U.S. in 1984 that called for a national network to coordinate the allocation of organs and collect clinical data about the organ donors, transplant candidates and transplant recipients.

Organ Procurement and Transplantation Network (OPTN) – A unique public-private partnership that links all professionals involved in the U.S. donation and transplantation system. Efforts are focused on patients with the goals to:

- Increase the number of and access to transplants.
- Improve survival rates after transplantation.
- Promote patient safety and efficient management of the system by maintaining transplant policies and bylaws.

Regions (Transplant) – For the administration of organ allocation and appropriate geographic representation within the OPTN policy structure, the membership is divided into 11 geographic regions. Members belong to the Region in which they are located. The Regions are as follows:

- Region 1: Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Eastern Vermont.
- Region 2: Delaware, District of Columbia, Maryland, New Jersey, Pennsylvania, West Virginia, and the part of Northern Virginia in the Donation Service Area served by the Washington Regional Transplant Community (DCTC) OPO.
- Region 3: Alabama, Arkansas, Florida, Georgia, Louisiana, Mississippi, Puerto Rico.
- Region 4: Oklahoma and Texas.
- Region 5: Arizona, California, Nevada, New Mexico, and Utah.
- Region 6: Alaska, Hawaii, Idaho, Montana, Oregon, and Washington.
- Region 7: Illinois, Minnesota, North Dakota, South Dakota, and Wisconsin.
- Region 8: Colorado, Iowa, Kansas, Missouri, Nebraska, and Wyoming.
- Region 9: New York and Western Vermont.
- Region 10: Indiana, Michigan, and Ohio.
- Region 11: Kentucky, North Carolina, South Carolina, Tennessee, and Virginia.

Scientific Registry of Transplant Recipients (SRTR) – Provides reports and data on solid organ transplantation.

United Network for Organ Sharing (UNOS) – Nonprofit organization which established a computerized database in 1977 that coordinates U.S. organ transplant activities. Their website contains information and statistics about organ transplantation by region, state and transplant center. UNOS was awarded the contract to develop the requirements for the operation of the OPTN since 1986.

7.0 References, Citations & Resources:

1. Organ Procurement and Transplantation Network (OPTN), Policies Administrative Rules and Definitions, 06/29/2017. Available at: <http://optn.transplant.hrsa.gov/>.
2. United Network for Organ Sharing (UNOS). Available at: <https://www.unos.org/>.

8.0 Associated Documents [For internal use only]:

Benefit Coverage Policies - BCP-33 Pre-Transplant Services.

Policies and Procedures (P&Ps) -MMP-02 Transition and Continuity of care; MMP-06 Peer-to-Peer Conversations; MM-09 Benefit determinations.

Standard Operating Procedures (SOPs) – MMS-03 Algorithm for Use of Criteria for Benefit Determinations; MMS-05 Completing a High Cost Notification; MMS-09 Case Management Referrals; MMS- 10 Pre-Transplant Process, MMS-11 Transplant Event and Listing, MMS-12 Post-Transplant Process.

Sample Letter – TCS Approval Letter; Clinically Reviewed Exclusion Letter; Specific Exclusion Denial Letter.

Form – Request Form: Out of Network/ Prior Authorization; High Cost Notification Form; Transplant Travel and Lodging Reimbursement Form.

9.0 Revision History:

Original Effective Date: 08/12/2009

Next Review Date: 07/01/2022

| Revision Date: | Reason for Revision |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| August 14, 2013 | Annual review and approval. |
| August 13, 2014 | Annual review and approval. |
| August 2015 | Annual review, revisions and approval. Standardized formatting, inserted General Background section, merged 4 sections under Clinical Determination Guidelines, added ICD-9 and ICD-10 codes. |
| July 2016 | Annual review and approval. Removed references to Medicaid/ DHHS, updated resources |
| July 2017 | Annual review – converted from Medical Policy 020 to Benefit Coverage Policy format |
| May 2018 | Annual review and approval. |
| June 2019 | Annual review; added criteria for transplant evaluation eligibility, criteria r/t HIV updated. |
| 8/14/19 | QI/MRM annual renewal and approval. |
| 4/20 | Annual review; approved by BCC 7/6/20, updated formatting and references |
| 4/21 | Annual review; removed backbench and unlisted procedure codes, updated references; criteria changed for A 6.g and D 1.d regarding smoking cessation; removed diagnosis code table; updated associated documents. |