Clinical Policy: Lung Transplantation

Reference Number: LA.CP.MP.57
Date of Last Revision: ~~2/22~~5/22

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Medical necessity criteria for the review of lung transplantation requests.

Policy/Criteria

I. It is the policy of Louisiana Healthcare Connections that lung transplantation for members/enrollees with chronic, end-stage lung disease who have failed maximal medical (including pulmonary rehabilitation, as applicable) or surgical therapy is **medically necessary** when all the following criteria are met:

A. High (> 50%) risk of death from lung disease within two years if lung transplantation is not performed;

B. High (> 80%) likelihood of five-year post-transplant survival from a general medical perspective provided there is adequate graft function;

C. Does not have ANY of the following absolute contraindications:[19]

1. Malignancy with high risk of recurrence or death related to cancer;
2. Glomerular filtration rate < 40 mL/min/1.73m^2 unless being considered for multi-organ transplant;
3. Acute renal failure with rising creatinine or on dialysis and low likelihood of recovery;
4. Acute liver failure, or cirrhosis with portal hypertension or synthetic dysfunction unless being considered for multi-organ transplant;
5. Stroke, acute coronary syndrome, or myocardial infarction (excluding demand ischemia) within 30 days;
6. Septic shock;
7. Active extrapulmonary or disseminated infection;
8. Active *tuberculosis* infection;
9. HIV infection with detectable viral load;
10. Progressive cognitive impairment;
11. Inability to adhere to the regimen necessary to preserve the transplant, even with caregiver support;
12. Other severe, uncontrolled medical condition expected to limit survival after transplant;
13. Active substance use or dependence (including current tobacco use, vaping, marijuana smoking, or intravenous drug use) without convincing evidence of risk reduction behaviors, such as meaningful and/or long-term participation in therapy for substance abuse and/or dependence. Serial blood and urine testing may be used to verify abstinence from substances that are of concern.
    a. If there is a history of nicotine or tobacco use, documentation notes abstinence from all tobacco and nicotine products (including nicotine replacement therapy) for ≥ 6 months prior to transplant.

~~**I.** It is the policy of Louisiana Healthcare Connections that lung transplant for~~

~~members/enrollees with chronic, end-stage lung disease who have failed maximal medical therapy is **medically necessary** when all of the following criteria are met:~~

~~**A.** High (> 50%) risk of death from lung disease within 2 years if lung transplantation is not performed.~~

~~**B.** High (> 80%) likelihood of surviving at least 90 days after lung transplantation.~~

~~**C.** High (> 80%) likelihood of 5-year post-transplant survival from a general medical perspective provided that there is adequate graft function.~~

D. Has one of the following disease states (not an all- inclusive list):
1. *Adult members/enrollees, age ≥ 18:*
   a. Interstitial lung disease and any of the following:*
      i. Absolute decline in forced vital capacity (FVC) ≥ 10% in the past 6 months despite appropriate treatment;
      ii. Absolute decline in diffusing capacity of the lung for carbon monoxide (DLCO) ≥10% in the past 6 months despite appropriate treatment;
      iii. Absolute decline in forced vital capacity (FVC) ≥ 5% with radiographic progression in the past 6 months despite appropriate treatment;
      iv. Desaturation to < 88% on 6-minute-walk test (6MWT) or > 50 m decline in 6MWT distance in the past 6-months;
      v. Pulmonary hypertension on right heart catheterization or 2-dimensional echocardiography (in the absence of diastolic dysfunction);
      vi. Hospitalization because of respiratory decline, pneumothorax, or acute exacerbation;
   b. Cystic fibrosis (CF) or other causes of bronchiectasis and any of the following:
      i. FEV1 <25% predicted despite optimal medical management including a trial of elexacaftor/tezacaftor/ivacaftor if eligible;
      ii. Both of the following:
         a) Any of the following despite optimal medical management including a trial of elexacaftor/tezacaftor/ivacaftor if eligible:
            1) FEV1 <30% predicted;
            2) FEV1 <40% predicted and any of the following:
               (a) Six-minute walk distance < 400 meters;
               (b) PaCO2 >50mmHg;
               (c) Hypoxemia at rest or with exertion;
               (d) Pulmonary hypertension (PA systolic pressure >50mmHg on echocardiogram or evidence of right ventricular dysfunction);
               (e) Worsening nutritional status despite supplementation;
               (f) 2 exacerbations per year requiring intravenous antibiotics;
               (g) Massive hemoptysis (>240 mL) requiring bronchial artery embolization;
               (h) Pneumothorax;
            3) FEV1 <50% predicted and rapidly declining based on pulmonary function testing or progressive symptoms;
            4) Any exacerbation requiring positive pressure ventilation;
         b) Any of the following:
            • Rapid decline in lung function or progressive symptoms (>30% relative

decline in FEV_1 over 12 months);
- Frequent hospitalization, particularly if >28 days hospitalized in the preceding year;
- Any exacerbation requiring mechanical ventilation;
- Chronic respiratory failure with hypoxemia or hypercapnia, particularly for those with increasing oxygen requirements or needing long-term non-invasive ventilation therapy;
- Pulmonary hypertension (Pulmonary arterial systolic pressure >50 mmHg on echocardiogram or evidence of right ventricular dysfunction);
- Worsening nutritional status particularly with BMI <18 kg/m^2 despite nutritional interventions;
- Recurrent massive hemoptysis despite bronchial artery embolization;
- World Health Organization (WHO) Functional Class IV;

c. Chronic obstructive pulmonary disease (COPD), and any of the following:
   i. BODE score (includes BMI, degree of airflow obstruction, degree of dyspnea, and exercise capacity) of 7-10;
   ii. FEV_1 (forced expiratory volume in 1 second) < 20% predicted;
   iii. History of severe exacerbations;
   iv. Chronic hypercapnia;
   v. Moderate to severe pulmonary hypertension;

d. Pulmonary vascular diseases and any of the following:
   i. European Society of Cardiology/European Respiratory Society (ESC/ERS) high risk or Registry to Evaluate Early and Long-term Pulmonary Arterial Hypertension Disease Management (REVEAL) risk score >10 on appropriate PAH therapy, including IV or SC prostacyclin analogues;
   ii. Progressive hypoxemia;
   iii. Progressive, but not end stage, liver or kidney dysfunction due to PAH
   iv. Life-threatening hemoptysis;

e. Eisenmenger syndrome with pulmonary hypertension despite therapy aimed at avoiding polycythemia, iron deficiency and dehydration, and the associated profound hypoxemia and impaired quality of life;

f. Lymphangioleiomyomatosis (LAM) with evidence of disease progression despite mTOR inhibitor therapy and any of the following:
   i. Severely abnormal lung function (e.g. FEV_1 <30% predicted);
   ii. Exertional dyspnea (NYHA class III or IV);
   iii. Hypoxemia at rest;
   iv. Pulmonary hypertension;
   v. Refractory pneumothorax;

g. Primary lung graft failure or bronchiolitis obliterans;

2. Pediatric members/enrollees, age < 18:

a. Cystic fibrosis, and any of the following:
   i. Progressive lung disease and disability despite optimal medical therapy;
   ii. FEV_1< 30% predicted;
   iii. Increasingly frequent hospitalizations;
   iv. Hypoxemia, (PaO_2 < 8 kPa or < 60 mm Hg);
   v. Hypercapnia, ($PaCO_2$ > 6.6 kPa or > 50 mmHg);

b. Idiopathic pulmonary arterial hypertension, and any of the following:
   i. European Pediatric Pulmonary Vascular Disease Network (EPPVDN) high risk category and on optimal therapy without improvement;

ii. Low exercise tolerance with 6MWT < 350 meters;
iii. Uncontrolled syncope;
iv. Hemoptysis;
v. Right-sided heart failure;
vi. Failure to respond to vasodilator therapy;

c. Pulmonary vascular disease and failure to respond to medical management;
d. Eisenmenger syndrome with pulmonary hypertension despite therapy aimed at avoiding polycythemia, iron deficiency and dehydration, and the associated profound hypoxemia and impaired quality of life;
e. Surfactant dysfunction disorders with unrelenting respiratory failure, or progressive interstitial lung disease with respiratory insufficiency, unresponsive to medical interventions;
f. Bronchopulmonary dysplasia, and any of the following:
i. Extended time requiring ventilator support without clinical improvement;
ii. Pulmonary hypertension unresponsive to oxygen therapy;
iii. Repeated episodes of respiratory failure without improvement in clinical trajectory over time, despite good medical support;
iv. Progressive pulmonary hypertension;
g. Diffuse parenchymal lung disease, and any of the following:
i. Disease progression despite optimal management;
ii. Poor quality of life;
h. Primary lung graft failure or bronchiolitis obliterans.

~~**D.** Does not have ANY of the following absolute contraindications:~~
~~1. Malignancy, except for non-melanoma localized skin cancer that has been treated appropriately, low grade prostate cancer, a malignancy that has been completely resected, or a treated malignancy determined to have a small likelihood of recurrence and acceptable future risks;~~
~~2. Untreatable significant dysfunction of another major organ system unless combined organ transplantation can be performed;~~
~~3. Uncorrected atherosclerotic disease with suspected or confirmed end-organ ischemia or dysfunction and/or coronary artery disease not amenable to revascularization;~~
~~4. Acute medical instability, including, but not limited to, acute sepsis, acute viral respiratory infection, myocardial infarction, and liver failure;~~
~~5. Uncorrectable bleeding diathesis;~~
~~6. Chronic infection with highly virulent and/or resistant microbes that are poorly controlled pre-transplant;~~
~~7. Evidence of active *Mycobacterium tuberculosis* infection and/or smear-positive non-tuberculous mycobacterial infection;~~
~~8. Significant chest wall/spinal deformity expected to cause severe restriction after transplantation;~~
~~9. Inability to adhere to the regimen necessary to preserve the transplant, even with caregiver support;~~
~~10. Class II or III obesity (body mass index ≥ 35.0 kg/m^2);~~
~~11. Absence of an adequate or reliable social support system;~~
~~12. Substance abuse or dependence (including tobacco and alcohol) without appropriate risk reduction behaviors, such as meaningful and/or long-term participation in therapy for substance abuse and/or dependence;~~
~~a. Documentation of abstinence from smoking for 6 months before consideration to be~~

eligible for transplant.

E. Has one of the following disease states and meets its corresponding criteria (not an all-inclusive list):

1. Adult members/enrollees, age ≥ 18:

a. Interstitial lung disease and any of the following:
   i. Decline in forced vital capacity (FVC) ≥ 10% during 6 months of follow-up (note: a 5% decline is associated with a poorer prognosis and may warrant listing);
   ii. Decline in diffusing capacity of the lung for carbon monoxide (DLCO) ≥15% during 6 months of follow-up;
   iii. Desaturation to < 88% or distance < 250 m on 6-minute-walk test (6MWT) or > 50 m decline in 6MWT distance over a 6-month period;
   iv. Pulmonary hypertension on right heart catheterization or 2-dimensional echocardiography;
   v. Hospitalization because of respiratory decline, pneumothorax, or acute exacerbation;

b. Cystic fibrosis (CF) or other causes of bronchiectasis, and any of the following:
   i. Chronic respiratory failure and one of the following:
      a) With hypoxia alone (partial pressure of oxygen [PaO_2] < 8 kPa or < 60 mm Hg);
      b) With hypercapnia (partial pressure of carbon dioxide [$PaCO_2$] > 6.6 kPa or > 50 mmHg);
   ii. Long-term non-invasive ventilation therapy;
   iii. Pulmonary hypertension;
   iv. Frequent hospitalization with a clinical trajectory of worsening quality of life and lung function;
   v. Rapid lung function decline;
   vi. World Health Organization (WHO) Functional Class IV.

c. Chronic obstructive pulmonary disease (COPD), and any of the following:
   i. BODE index (includes BMI, degree of airflow obstruction, degree of dyspnea, and exercise capacity) ≥ 7;
   ii. FEV1 (forced expiratory volume in 1 second) < 15 to 20% of predicted;
   iii. Three or more severe exacerbations during the preceding year;
   iv. At least one severe exacerbation with acute hypercapnic respiratory failure;
   v. Moderate to severe pulmonary hypertension;

d. Pulmonary vascular diseases and any of the following:
   i. New York Heart Association (NYHA) Functional Class III or IV despite a trial of at least 3 months of combination therapy including prostanoids;
   ii. Cardiac index of < 2 liters/min/m2;
   iii. Mean right atrial pressure > 15 mm Hg;
   iv. 6MWT of < 350 m;
   v. Development of significant hemoptysis, pericardial effusion, or signs of progressive right heart failure (renal insufficiency, increasing bilirubin, brain natriuretic peptide, or recurrent ascites);

e. Eisenmenger syndrome with pulmonary hypertension despite therapy aimed at avoiding polycythemia, iron deficiency and dehydration, and the associated profound hypoxemia and impaired quality of life;

f. Lymphangioleiomyomatosis and any of the following:

i. Severe impairment in lung function and exercise capacity (e.g., VO2 max <50% predicted);
ii. Hypoxemia at rest;

g. Primary lung graft failure or bronchiolitis obliterans.

2. *Pediatric members/enrollees, age < 18:*

a. Cystic fibrosis, and any of the following:
i. Progressive lung disease and disability despite optimal medical therapy;
ii. FEV1 < 30%;
iii. Increasingly frequent hospitalizations;
iv. Hypoxemia, (PaO_2 < 8 kPa or < 60 mm Hg);
v. Hypercapnia, ($PaCO_2$ > 6.6 kPa or > 50 mmHg);

b. Idiopathic pulmonary arterial hypertension, and any of the following:
i. NYHA or WHO functional class III or IV despite vasodilator therapy;
ii. Low exercise tolerance with 6MWT < 350 meters;
iii. Uncontrolled syncope;
iv. Hemoptysis;
v. Right-sided heart failure;
vi. Failure to respond to vasodilator therapy;

c. Pulmonary vascular disease and failure to respond to medical management;

d. Eisenmenger syndrome with pulmonary hypertension despite therapy aimed at avoiding polycythemia, iron deficiency and dehydration, and the associated profound hypoxemia and impaired quality of life;

e. Surfactant dysfunction disorders with unrelenting respiratory failure, or progressive interstitial lung disease with respiratory insufficiency, unresponsive to medical interventions;

f. Bronchopulmonary dysplasia, and any of the following:
i. Extended time requiring ventilator support without clinical improvement;
ii. Pulmonary hypertension unresponsive to oxygen therapy;
iii. Repeated episodes of respiratory failure without improvement in clinical trajectory over time, despite good medical support;
iv. Progressive pulmonary hypertension;

g. Diffuse parenchymal lung disease, and any of the following:
i. Disease progression despite optimal management;
ii. Poor quality of life;

h. Primary lung graft failure or bronchiolitis obliterans.

Background

Lung transplantation is an accepted therapy for the management of a range of severe lung disorders. Single, double, and lobar-lung transplants have all been successful for carefully selected patients with end-stage pulmonary disease. The most common disease processes for which lung transplants are performed include COPD, idiopathic pulmonary fibrosis, cystic fibrosis, pulmonary arterial hypertension, and sarcoidosis.

COPD is one of the most common lung diseases and is the most common indication for lung transplantation. Chronic bronchitis and emphysema are the two main forms of COPD, both most commonly caused from smoking. Non-smokers with an alpha-1 antitrypsin deficiency can also develop emphysema. These conditions are the most common indications for single lung transplants. Cystic fibrosis, emphysema, and alpha-1 antitrypsin deficiency are the most common indications for double lung transplant, or sequential replacement of both lungs.

The most common indications for pediatric lung transplants include pulmonary vascular disease, bronchiolitis obliterans, bronchopulmonary dysplasia, graft failure due to viral pneumonitis, and CF.

Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2019, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only and may not support medical necessity and may not support medical necessity. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

CPT® Codes	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

HCPCS Codes	Description
S2060	Lobar lung transplantation
S2152	Solid organ(s), complete or segmental, single organ or combination of organs; deceased or living donor (s), procurement, transplantation, and related complications; including: drugs; supplies; hospitalization with outpatient follow-up; medical/surgical, diagnostic, emergency, and rehabilitative services, and the number of days of pre- and post-transplant care in the global definition

ICD-10-CM Diagnosis Codes that Support Coverage Criteria

ICD-10-CM Code	Description
C96.6	Unifocal Langerhans-cell histiocytosis
D86.0	Sarcoidosis of lung
E84.0-E84.9	Cystic fibrosis
E88.01	Alpha-1-antitrypsin deficiency
I27.0	Primary pulmonary hypertension
I27.23	Pulmonary hypertension due to lung diseases and hypoxia
I27.83	Eisenmenger's syndrome
I27.89	Other specified pulmonary heart disease
I27.9	Pulmonary heart disease, unspecified
J41.8	Mixed simple and mucopurulent chronic bronchitis

ICD-10-CM Code	Description
J42	Unspecified chronic bronchitis
J43.0-J43.9	Emphysema
J44.0-J44.9	Other chronic obstructive pulmonary disease
J47.0-J47.9	Bronchiectasis
J60	Coal worker's Pneumoconiosis
J61	Pneumoconiosis due to asbestos and other mineral fibers
J62.0-J62.8	Pneumoconiosis due to dust containing silica
J63.0-J63.6	Pneumoconiosis due to other inorganic dusts
J84.10	Pulmonary fibrosis, unspecified
J84.111-J84.17	Idiopathic interstitial pneumonia
J84.81	Lymphangioleiomyomatosis
J84.82	Adult pulmonary Langerhans cell histiocytosis
J84.83	Surfactant mutations of the lung
J84.89	Other specified interstitial pulmonary disease
J98.2	Interstitial emphesema
J99	Respiratory disorders in diseases classified elsewhere
P27.0-P27.9	Chronic respiratory disease originating in the perinatal period
Q21.8	Other congenital malformations of cardiac septa
Q33.0-Q33.9	Congenital malformations of the lung
T86.810-T86.819	Complications of lung transplant
Z99.89	Dependence on other enabling machines and devices

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Converted corporate to local policy.	08/15/2020	
References reviewed and updated. Replaced "members" with "members/enrollees" in all instances. Replaced contraindications of "severely limited functional status with poor rehabilitation potential" and those regarding past or current nonadherence to medical therapy, and psychological condition associated with the inability to comply with medical therapy with "Inability to adhere to the regimen necessary to preserve the transplant, even with caregiver support." Changed "review date" in header to "Date of Last Revision" and "Date" in the revision log header to "Revision Date." Added "and may not support medical necessity" in coding implications. Annual review. References reviewed and updated. Reviewed by specialist.	2/22	
Annual review. Added "or surgical therapy" to I and noted that maximal medical therapy includes pulmonary rehab when applicable. Updated the following based on ISHLT 2021 guidelines; removed criteria "High (> 80%) likelihood of surviving at least 90 days after lung transplantation.", updated I.C., I.D.1.a, I.D.1.b., I.D.1.c., I.D.1.d., I.D.1.f., I.D.2.a, I.D.2.b. Clarified nicotine and tobacco abstinence contraindication. Added CPT codes 32850, 32855, and 32856.	5/22	

Reviews, Revisions, and Approvals	Revision Date	Approval Date
References reviewed, updated, and reformatted. Reviewed by specialist. Added "and may not support medical necessity" to Coding Implications section		

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Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. LHCC retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom LHCC has no control or right of control. Providers are not agents or employees of LHCC.

for such services.