Clinical Policy: Lung Transplantation

Reference Number: LA.CP.MP.57
Date of Last Revision: 03/25

Coding Implications
Revision Log

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

Description
This policy describes the medical necessity criteria for the review of lung transplantation requests.

The below criteria are sourced from the International Society for Heart and Lung Transplantation (ISHLT) 2021 Consensus Document for the Selection of Lung Transplant Candidates.[1]

The ISHLT consensus document that the below criteria are derived from provides guidelines based on expert synthesis of the current literature with a goal of improving survival and quality of life in transplant candidates. ISHLT recognizes that donor lungs are a limited societal resource, requiring that guidance on candidate selection be based on survival benefit. Given the rigor of the guidelines on which this policy is based, the benefits of receiving a lung transplant in individuals meeting the criteria below outweighs the potential risk of adverse outcomes related to receiving a transplant that is not indicated or not receiving a transplant that is indicated.

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[1];
- B. High (> 80%) likelihood of five-year post-transplant survival from a general medical perspective provided there is adequate graft function[1];
- C. Does not have ANY of the following absolute contraindications[1]:
  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[1];
  3. Acute renal failure with rising creatinine 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 unless all of the following are noted:
     a. CD4 cell count >200 cells/mm3 for at least three months before transplantation[2];
     b. Absence of active AIDS-defining opportunistic infection or malignancy[2];
     c. Member/enrollee is currently on effective antiretroviral therapy (ART)[2,3,4];
     d. Member/enrollee does not have chronic wasting or severe malnutrition[2];

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 use [unless prescribed by a licensed practitioner], or intravenous drug use) without convincing evidence of risk reduction behaviors (unless urgent transplant timelines are present, in which case a commitment to reducing behaviors is acceptable). Serial blood and urine testing may be used to verify abstinence from substances that are of concern[1,2];
14. History of nicotine, tobacco, alcohol, or illicit drug use, without documentation noting abstinence from all (including nicotine replacement therapy) for ≥ six months prior to transplant[2];

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[1]:*
         i. Absolute decline in forced vital capacity (FVC) > 10% in the past six months despite appropriate treatment;
         ii. Absolute decline in diffusing capacity of the lung for carbon monoxide (DLCO) > 10% in the past six months despite appropriate treatment;
         iii. Absolute decline in forced vital capacity (FVC) > 5% with radiographic progression in the past six months despite appropriate treatment;
         iv. Desaturation to < 88% on six-minute-walk test (6MWT) or > 50 m decline in 6MWT distance in the past six months;
         v. Pulmonary hypertension on right heart catheterization or two 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[1]:
         i. FEV_1 < 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) FEV_1 < 30% predicted;
               2) FEV_1 < 40% predicted and any of the following:
                  i) Six-minute walk distance < 400 meters;
                  ii) P_aCO2 > 50 mmHg;
                  iii) Hypoxemia at rest or with exertion;
                  iv) Pulmonary hypertension (PA systolic pressure > 50 mmHg on echocardiogram or evidence of right ventricular dysfunction);
                  v) Worsening nutritional status despite supplementation;
                  vi) Two exacerbations per year requiring intravenous antibiotics;
                  vii) Massive hemoptysis (>240 mL) requiring bronchial artery embolization;
                  viii) Pneumothorax;
               3) FEV_1 <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[1]:

1) Rapid decline in lung function or progressive symptoms (>30% relative decline in FEV_1 over 12 months);
2) Frequent hospitalization, particularly if > 28 days hospitalized in the preceding year;
3) Any exacerbation requiring mechanical ventilation;
4) Chronic respiratory failure with hypoxemia or hypercapnia, particularly for those with increasing oxygen requirements or needing long-term non-invasive ventilation therapy;
5) Pulmonary hypertension (pulmonary arterial systolic pressure >50 mmHg on echocardiogram or evidence of right ventricular dysfunction);
6) Worsening nutritional status particularly with body mass index (BMI) <18 kg/m^2 despite nutritional interventions;
7) Recurrent massive hemoptysis despite bronchial artery embolization;
8) World Health Organization (WHO) Functional Class IV;

c. Chronic obstructive pulmonary disease (COPD), and any of the following[1]:

i. BODE score (includes BMI, degree of airflow obstruction, degree of dyspnea, and exercise capacity) of 7 to 10;
ii. FEV_1 (forced expiratory volume in one 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[1]:

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 pulmonary arterial hypertension (PAH) therapy, including intravenous (IV) or subcutaneous (SC) prostacyclin analogues;
ii. Progressive hypoxemia;
iii. Progressive, but not end stage, liver, or kidney dysfunction due to PAH
iv. Life-threatening hemoptysis;
v. PAH in the European Pediatric Pulmonary Vascular Disease Network (EPPVDN) high risk category and on optimal therapy without improvement[1];

e. Lymphangioleiomyomatosis (LAM) with evidence of disease progression despite mTOR inhibitor therapy and any of the following[1]:

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;

f. Primary lung graft failure;

g. Acute respiratory distress syndrome (ARDS) with a persistent requirement for mechanical ventilatory support and /or extracorporeal life support (ECLS) without expectation of clinical recovery and with evidence of irreversible lung destruction[1];

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

a. Cystic fibrosis, and any of the following[1]:

i. FEV_1 < 30% predicted despite optimal medical management including a trial of elexacaftor/tezacaftor/ivacaftor if eligible[1];

ii. Both of the following[1]:
  a) Any of the following despite optimal medical management including a trial of elexacaftor/tezacaftor/ivacaftor if eligible:
    1) FEV_1 < 40% predicted[1];
    2) FEV_1 < 50% predicted and any of the following[1]:
      i) Six-minute walk distance < 400 meters;
      ii) P_aCO2 > 50 mmHg;
      iii) Hypoxemia at rest or with exertion;
      iv) Pulmonary hypertension (PA systolic pressure > 50 mmHg on echocardiogram or evidence of right ventricular dysfunction;
      v) Worsening nutritional status despite supplementation;
      vi) Two exacerbations per year requiring intravenous antibiotics;
      vii) Massive hemoptysis (>240 mL) requiring bronchial artery embolization;
      viii) Pneumothorax;
    3) FEV_1 <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[1]:
    1) Rapid decline in lung function or progressive symptoms (>30% relative decline in FEV_1 over 12 months);
    2) Frequent hospitalization, particularly if > 28 days hospitalized in the preceding year;
    3) Any exacerbation requiring mechanical ventilation;
    4) Chronic respiratory failure with hypoxemia or hypercapnia, particularly for those with increasing oxygen requirements or needing long-term non-invasive ventilation therapy;
    5) Pulmonary hypertension (pulmonary arterial systolic pressure >50 mmHg on echocardiogram or evidence of right ventricular dysfunction);
    6) Worsening nutritional status particularly with BMI <18 kg/m2 despite nutritional interventions;
    7) Recurrent massive hemoptysis despite bronchial artery embolization;
    8) WHO Functional Class IV;

b. Pulmonary vascular disease and any of the following[1]:
  i. 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;

c. Interstitial lung disease and any of the following[1]:
  i. Absolute decline in FVC > 10% in the past six months despite appropriate treatment;
  ii. Absolute decline in DLCO > 10% in the past six months despite appropriate treatment;
  iii. Absolute decline in FVC > 5% with radiographic progression in the past six months despite appropriate treatment;
  iv. Desaturation to < 88% on 6MWT or > 50 m decline in 6MWT distance

in the past six months;
v. Pulmonary hypertension on right heart catheterization or two dimensional echocardiography (in the absence of diastolic dysfunction);
vi. Hospitalization because of respiratory decline, pneumothorax, or acute exacerbation;

d. COPD, and any of the following[1]:
i. BODE score (includes BMI, degree of airflow obstruction, degree of dyspnea, and exercise capacity) of 7 to 10;
ii. FEV_1 < 20% predicted;
iii. History of severe exacerbations;
iv. Chronic hypercapnia;
v. Moderate to severe pulmonary hypertension;

e. Primary lung graft failure[1];
f. LAM with evidence of disease progression despite mTOR inhibitor therapy and any of the following[1]:
i. Several abnormal lung function (e.g. FEV1 <30% predicted);
ii. Exertional dyspnea (NYHA class III or IV);
iii. Hypoxemia at rest;
iv. Pulmonary hypertension;
v. Refractory pneumothorax;

g. ARDS with a persistent requirement for mechanical ventilatory support and /or ECLS without expectation of clinical recovery and with evidence of irreversible lung destruction[1];
h. Alveolar capillary dysplasia[1];
i. Pulmonary vein stenosis refractory to intervention[1];
j. Pulmonary veno-occlusive disease.[1]

**Note:* FVC may be a less reliable parameter for those with concomitant emphysema.[1]

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 chronic obstructive pulmonary disease (COPD), idiopathic pulmonary fibrosis, cystic fibrosis, pulmonary arterial hypertension, and sarcoidosis.[5]

COPD is one of the most common lung diseases and is the most common indication for lung transplantation in adults. Chronic bronchitis and emphysema are the two main forms of COPD, both most commonly caused by 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 cystic fibrosis.

Coding Implications

NOTE: Coverage is subject to each requested code's inclusion on the corresponding LDH fee schedule. Non-covered codes are denoted (*) and are reviewed for Medical Necessity for members under 21 years of age on a per case basis.

CPT® Codes	Description
32850	Donor pneumonectomy(s) (including cold preservation), from cadaver donor
32851	Lung transplant, single; without cardiopulmonary bypass
32852	Lung transplant, single; with cardiopulmonary bypass
32853	Lung transplant, double (bilateral sequential or en bloc); without cardiopulmonary bypass
32854	Lung transplant, double (bilateral sequential or en bloc); with cardiopulmonary bypass
32855*	Backbench standard preparation of cadaver donor lung allograft prior to transplantation, including dissection of allograft from surrounding soft tissues to
32856*	Backbench standard preparation of cadaver donor lung allograft prior to transplantation, including dissection of allograft from surrounding soft tissues to

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

Reviews, Revisions, and Approvals	Revision Date	Approval Date	Effective Date
Converted corporate to local policy.	08/15/20		
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	2/22		

Reviews, Revisions, and Approvals	Revision Date	Approval Date	Effective Date
"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.			
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. References reviewed, updated, and reformatted. Reviewed by specialist. Added "and may not support medical necessity" to Coding Implications section	5/22	8/13/22	
Annual review. Criteria I.C.14. updated to exclude marijuana use when prescribed by a licensed practitioner and include required commitment to reducing substance use behaviors if urgent transplant timelines are present. Added pediatric indication for end-stage emphysema due to alpha-1 trypsin deficiency. ICD-10 codes removed. References reviewed and updated. Reviewed by external specialist.	4/23	7/21/23	
Revised adult and pediatric criteria to align with ISHLT 2021 consensus document. References reviewed and updated. Note for non-covered codes added.	09/23	11/27/23	12/27/23
Annual review. Updated I.C.2. from GFR < 40 mL/min/1.73m2 to GFR < 30 mL/min/1.73m2. Expanded I.C.9. with qualifying criteria for members who are HIV positive. Updated I.D.2.a.1. from FEV_1<25% to FEV_1<30%. Background updated with no impact to criteria. References reviewed and updated.	05/24	7/16/24	8/16/24
Annual review. Updated glomerular filtration rate from < 30 to < 40 mL/min/1.73m2 in Criteria I.C.2. Updated Criteria I.C.9.a. to include at least three months prior to transplantation. Removed additional information regarding heart transplant waiting list in Criteria I.C.9.b. Minor grammatical update in Criteria I.C.9.c. Added Criteria I.C.9.d. regarding chronic wasting or severe malnutrition. Expanded Criteria I.C.13. regarding active substance use or dependence and added Criteria I.C.14. regarding documentation of abstinence from substance use. Minor grammatical changes to Criteria I.D.1.b.ii.b)5), Criteria I.D.1.c.i., Criteria I.D.2., Criteria I.D.2.a.ii.b)5), and Criteria I.D.2.d.i. with no clinical significance. Added Criteria I.D.2.h., Criteria I.D.2.i, and Criteria I.D.2.j. regarding alveolar capillary dysplasia, pulmonary vein stenosis refractory to intervention, and pulmonary veno-occlusive disease. Background updated with no impact to criteria. References reviewed and updated. Reviewed by internal specialist and external specialist.	3/25	5/20/25	6/19/25

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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.

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