

# Clinical Policy: Lung Transplantation

Reference Number: CP.MP.57

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## Description

Medical necessity criteria for the review of lung transplantation requests.

## Policy/Criteria

- I. It is the policy of health plans affiliated with Centene Corporation<sup>®</sup> 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:<sup>19</sup>
    1. Malignancy with high risk of recurrence or death related to cancer;
    2. Glomerular filtration rate < 40 mL/min/1.73m<sup>2</sup> 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 use (unless prescribed by a licensed practitioner), or IV 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.
      - 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 ≥ six months prior to transplant.
  - D. Has one of the following disease states (not an all- inclusive list):
    1. *Adult members/enrollees, age ≥ 18:*

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- a. Interstitial lung disease and any of the following: \*
  - i. Absolute decline in forced vital capacity (FVC)  $\geq 10\%$  in the past six months despite appropriate treatment;
  - ii. Absolute decline in diffusing capacity of the lung for carbon monoxide (DLCO)  $\geq 10\%$  in the past six months despite appropriate treatment;
  - iii. Absolute decline in forced vital capacity (FVC)  $\geq 5\%$  with radiographic progression in the past 6 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:
  - 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) PaCO<sub>2</sub>  $> 50$  mmHg;
        - (c) Hypoxemia at rest or with exertion;
        - (d) Pulmonary hypertension (PA systolic pressure  $> 50$  mmHg on echocardiogram or evidence of right ventricular dysfunction);
        - (e) Worsening nutritional status despite supplementation;
        - (f) Two 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:
      - 1) Rapid decline in lung function or progressive symptoms ( $> 30\%$  relative decline in FEV<sub>1</sub> 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/m<sup>2</sup> despite nutritional interventions;
      - 7) Recurrent massive hemoptysis despite bronchial artery embolization;
      - 8) World Health Organization (WHO) Functional Class IV;

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- 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 to 10;
    - ii. FEV<sub>1</sub> (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:
    - 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. Lymphangiomyomatosis (LAM) with evidence of disease progression despite mTOR inhibitor therapy and any of the following:
    - i. Severely abnormal lung function (e.g. FEV<sub>1</sub> <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<sub>1</sub> < 30% predicted;
    - iii. Increasingly frequent hospitalizations;
    - iv. Hypoxemia, (PaO<sub>2</sub> < 8 kPa or < 60 mm Hg);
    - v. Hypercapnia, (PaCO<sub>2</sub> > 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:

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- 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;
- i. End-stage emphysema due to alpha-1 trypsin deficiency.

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

**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 in adults. 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 cystic fibrosis.

**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 2022, 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. 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
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

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<b>CPT® Codes</b>	<b>Description</b>
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

<b>HCPCS Codes</b>	<b>Description</b>
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

<b>Reviews, Revisions, and Approvals</b>	<b>Revision Date</b>	<b>Approval Date</b>
Policy developed. Specialist review.	01/14	02/14
Added Eisenmenger syndrome as a qualifying condition for adult transplant. Added that the list of qualifying conditions for transplant is not all-inclusive. Added primary lung graft failure and bronchiolitis obliterans as an indication for adult and pediatric transplant since ISHLT guidelines recommend retransplant in certain cases. Updated coding. Added time frame for which smoking cessation should be documented.	11/17	11/17
In criteria pertaining to substance use, removed the statement that serial blood and urine testing” may be required, as it is informational only. In the adult COPD criteria, changed “one severe exacerbation” to “at least one severe exacerbation.”	06/18	
References reviewed and updated.	10/18	10/18
References reviewed and updated. Specialist review	08/19	09/19
Edited malignancy contraindication to not specify within 2 years, and added exceptions of early-stage prostate cancer, cancer that has been completely resected, or that has been treated and poses acceptable future risk.	05/20	05/20
References reviewed and updated. Replaced “members” with “members/enrollees” in all instances.	09/20	09/20
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	08/21	08/21

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Reviews, Revisions, and Approvals	Revision Date	Approval Date
Date.”		
Annual review. References reviewed and updated. Reviewed by specialist.	09/21	09/21
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.	02/22	02/22
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.	02/23	02/23

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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. The Health Plan 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. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

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

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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 Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. 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. The Health Plan 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 the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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**Note: For Medicaid members/enrollees**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

**Note: For Medicare members/enrollees**, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at <http://www.cms.gov> for additional information.

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