

# EVH Clinical Guideline 2702.CC for Transplant: Lung and Lobar Lung

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## STATEMENT

### General Information

- *It is an expectation that all members receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines, and state/national recommendations.*
- *The guideline criteria in the following sections were developed utilizing evidence-based and peer-reviewed resources from medical publications and societal organization guidelines as well as from widely accepted standard of care, best practice recommendations.*

## INDICATIONS

CountyCare considers **Lung and Lobar Lung Transplants** medically necessary for the following indications:

### General Criteria for Lung and Lobar Lung Transplant

In adult population with chronic, progressive, and disabling end-stage lung disease who meet ALL of the following <sup>(1)</sup>:

- Member meets the institution's selection criteria for lung or lung lobar transplantation
- High (>50%) risk of death from lung disease within 2 years if lung transplantation is not performed
- High (>80%) likelihood of 5-year post-transplant survival from a general medical perspective provided that there is adequate graft function
- Failing maximum evidence-based medical therapy, or for whom no medical therapy exists
- Demonstrating adequate health behaviors, the willingness and ability to adhere to complex post-transplant medical regimens and follow-up with health care professionals

In pediatric population who meet any of the following <sup>(1)</sup>:

- Member meets the institution's selection criteria for lung or lung lobar transplantation
- Cystic fibrosis (CF) <18 years of age with FEV1 <30% predicted
- Pulmonary arterial hypertension (PAH) <18 years of age in European Pediatric Pulmonary Vascular Disease Network (EPPVDN) high risk category and on optimal

therapy without improvement

## Disease Specific Criteria

### *Interstitial Lung Disease (ILD)* <sup>(1)</sup>

#### Timing of Referral

- Referral should be made at time of diagnosis, even if a member is being initiated on therapy, for histopathological usual interstitial pneumonia (UIP) or radiographic evidence of a probable or definite UIP pattern
- Any form of pulmonary fibrosis with forced vital capacity (FVC) of < 80% predicted or diffusion lung capacity for carbon monoxide (DLCO) < 40% predicted
- Any form of pulmonary fibrosis with ONE of the following in the past 2 years:
  - Relative decline in FVC 10%
  - Relative decline in DLCO 15%
  - Relative decline in FVC 5% in combination with worsening of respiratory symptoms or radiographic progression
- Supplemental oxygen requirement either at rest or on exertion
- For inflammatory ILDs, progression of disease (either on imaging or pulmonary function) despite treatment
- For members with connective tissue disease or familial pulmonary fibrosis, early referral is recommended as extrapulmonary manifestations may require special consideration

#### Timing of Listing

- Any form of pulmonary fibrosis with one of the following in the past 6 months despite appropriate treatment:
  - Absolute decline in forced vital capacity (FVC) > 10%
  - Absolute decline in DLCO >10%
  - Absolute decline in FVC > 5% with radiographic progression
- Desaturation to < 88% on 6-minute walk test or > 50 m decline in 6-minute walk test distance in the past 6 months
- Pulmonary hypertension on right heart catheterization or 2-dimensional echocardiography (in the absence of diastolic dysfunction)
- Hospitalization because of respiratory decline, pneumothorax, or acute exacerbation

**NOTE:** For members with concomitant emphysema, a decline in FVC is a less reliable parameter compared to other markers progression of disease on CT scan or DLCO, or development of secondary pulmonary hypertension

## ***Chronic Obstructive Pulmonary Diseases (COPD) <sup>(1)</sup>***

### **Timing of Referral**

- Body Mass Index, Airflow Obstruction, Dyspnea and Exercise Capacity (BODE) score 5-6 with additional factor(s) present suggestive of increased risk of mortality:
  - Frequent acute exacerbations
  - Increase in BODE score >1 over past 24 months
  - Pulmonary artery to aorta diameter > 1 on CT scan
  - Forced expiratory volume in 1 second (FEV1) 20-25% predicted
- Clinical deterioration despite maximal treatment including medication, pulmonary rehabilitation, oxygen therapy, and as appropriate, nocturnal non-invasive positive pressure ventilation
- Poor quality of life unacceptable to the member
- For a member who is a candidate for bronchoscopic or surgical lung volume reduction (LVR), simultaneous referral for both lung transplant and LVR evaluation is appropriate

### **Timing of Listing**

- Members with a BODE index of  $\geq 7$  and at least one of the following:
  - FEV1 < 20% predicted
  - Presence of moderate to severe pulmonary hypertension
  - History of severe exacerbation
  - Chronic hypercapnia

## ***Pulmonary Arterial Hypertension (PAH)***

### **Timing of Referral**

- European Society of Cardiology/European Respiratory Society (ESC/ERS) intermediate or high risk or Registry to Evaluate Early and Long-term Pulmonary Arterial Hypertension Disease Management (REVEAL) risk score 8 despite appropriate PAH therapy
- Significant RV dysfunction despite appropriate PAH therapy
- Need for IV or SC prostacyclin therapy
- Progressive disease despite appropriate therapy or recent hospitalization for worsening of PAH
- Known or suspected high-risk variants such as PVOD/PCH, scleroderma, large and progressive pulmonary artery aneurysms
- Signs of secondary liver or kidney dysfunction due to PAH
- Potentially life-threatening complications such as recurrent hemoptysis

### Timing of Listing

- ESC/ERS high risk <sup>(2)</sup> or REVEAL risk <sup>(3)</sup> score >10 on appropriate PAH therapy, including IV or SC prostacyclin analogues
- Progressive hypoxemia, especially in members with pulmonary veno-occlusive disease (PVOD) or pulmonary capillary hemangiomatosis (PCH)
- Progressive, but not end-stage, liver or kidney dysfunction due to PAH
- Life-threatening hemoptysis

### ***Cystic Fibrosis (CF) and other causes of Bronchiectasis <sup>(1)</sup>***

#### Timing of Referral

- ANY of the following below despite optimal medical management including a trial of elxacaftor/tezacaftor/ivacaftor:
  - FEV1 < 30% predicted in adults (or < 40% predicted in children)
  - FEV1 <40% predicted in adults (or <50% predicted in children) and any of the following:
    - 6-minute walk distance < 400 m
    - PaCO<sub>2</sub> > 50 mmHg
    - Hypoxemia at rest or with exertion
    - Pulmonary hypertension (PA systolic pressure > 50 mmHg on echocardiogram or evidence of right ventricular dysfunction)
    - Worsening nutritional status despite supplementation
    - 2 exacerbations per year requiring intravenous antibiotics
    - Massive hemoptysis (>240 mL) requiring bronchial artery embolization
    - Pneumothorax
  - FEV1 < 50% predicted and rapidly declining based on pulmonary function testing or progressive symptoms
  - Any exacerbation requiring positive pressure ventilation

#### Timing of Listing

- Any of the above referral criteria AND any of the below criteria:
  - FEV1 <25% predicted
  - Rapidly declining lung function or progressive symptoms (>30% relative decline in FEV1 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<sup>2</sup> despite nutritional interventions
  - Recurrent massive hemoptysis despite bronchial artery embolization
  - World Health Organization (WHO) functional class IV

**NOTE:** All transplant candidates with CF should be evaluated for *Burkholderia cepacia* complex, non-tuberculous mycobacteria, and fungal pathogens

### ***Lymphangiomyomatosis (LAM) <sup>(1)</sup>***

#### **Timing of Referral**

- For any members with LAM who have ANY of the following despite mTOR inhibitor therapy:
  - Severely abnormal lung function (e.g. FEV<sub>1</sub> < 30% predicted)
  - Exertional dyspnea (NYHA class III or IV)
  - Hypoxemia at rest
  - Pulmonary hypertension
  - Refractory pneumothorax

#### **Timing of Listing**

- Listing for lung transplantation should occur for an individual with LAM who meets the above referral criteria and has evidence of disease progression despite mTOR inhibitor therapy
- Cessation of mTOR inhibitor therapy should occur at the time of transplant but cessation should not be required for placement on the waiting list. It may be preferable to use everolimus and target trough levels in the lower therapeutic range for members on the waiting list.

### ***Acute Respiratory Distress Syndrome (ARDS) <sup>(1)</sup>***

- Persistent requirement for mechanical ventilatory support and /or extracorporeal life support (ECLS) without expectation of clinical recovery and with evidence of irreversible lung destruction

### ***Specific Criteria for Lung and Lobar Lung Transplant in HIV+ Members <sup>(4,5)</sup>***

Lung-lobar lung transplantation in HIV+ **recipients** is considered medically necessary when ALL of the following conditions are met:

- CD4+ count  $\geq$  200 cells/mL for 3 months prior to transplantation
- Undetectable HIV viremia ( $<$  50 copies/mL) for at least 3 months while receiving antiretroviral therapy
- Documented compliance with a stable antiretroviral therapy (HAART) regimen
- Absence of active opportunistic infection and malignancy
- Absence of chronic wasting or severe malnutrition
- Appropriate follow-up with providers experienced in management of HIV
- Available antiretroviral treatment options post-transplant

### **Connective Tissue Disorder** <sup>(1,6)</sup>

- Required a multidisciplinary approach for a comprehensive extrapulmonary screening and should be considered on a case-by-case basis

## **LIMITATIONS**

- All other medical and surgical therapies that might be expected to yield both short- and long-term survival comparable to that of transplantation must have been tried or considered.
- Members must first undergo stringent physical and psychological evaluation to determine eligibility for transplant. Members should have no other serious medical problems, and they should be psychologically willing to undergo the stressful surgery and postoperative care necessary.
- Living Donors for lobar lung transplantation must be capable of giving informed consent, have no cardiopulmonary abnormalities or history of thoracic surgery on the donor lung side, and must be currently a nonsmoker for six months. Transplant centers must ensure that the prospective donor has been informed regarding the aspects of living donation and possible outcomes.
- Xenotransplants of lung or lobar lung for any condition is considered experimental and investigational (e.g., porcine xenografts).
- Chronic high-dose steroid therapy due to impairment of bronchial healing.

### **High Risk Factors with Unfavorable Implications for Short and/or Long-Term Outcomes After Lung Transplant** <sup>(1)</sup>

- Age  $>$  70 years
- Severe coronary artery disease that requires coronary artery bypass grafting at transplant
- Reduced left ventricular ejection fraction  $<$  40%

- Significant cerebrovascular disease
- Severe esophageal dysmotility
- Untreatable hematologic disorders including bleeding diathesis, thrombophilia, or severe bone marrow dysfunction
- BMI  $\geq$  35 kg/m<sup>2</sup>
- BMI  $<$  16 kg/m<sup>2</sup>
- Limited functional status with potential for post-transplant rehabilitation
- Psychiatric, psychological or cognitive conditions with potential to interfere with medical adherence without sufficient support systems
- Unreliable support system or caregiving plan
- Lack of understanding of disease and / or transplant despite teaching
- *Mycobacterium abscessus* infection
- *Lomentospora prolificans* infection
- *Burkholderia cenocepacia* or gladioli infection
- Hepatitis B or C infection with detectable viral load and liver fibrosis
- Chest wall or spinal deformity expected to cause restriction after transplant
- Extracorporeal life support
- Retransplant  $<$  1 year following initial lung transplant
- Retransplant for restrictive chronic lung allograft dysfunction (CLAD)
- Retransplant for AMR as etiology for CLAD

## **ABSOLUTE CONTRAINDICATIONS <sup>(1)</sup>**

- Lack of member willingness or acceptance of transplant
- Malignancy with high risk of recurrence or death related to cancer
- Glomerular filtration rate  $<$  40 mL/min/1.73 m<sup>2</sup> unless being considered for multi-organ transplant
- Acute coronary syndrome or myocardial infarction within 30 days (excluding demand ischemia)
- Stroke within 30 days
- Liver cirrhosis with portal hypertension or synthetic dysfunction unless being considered for multi-organ transplant
- Acute liver failure

- Acute renal failure with rising creatinine or on dialysis and low likelihood of recovery
- Septic shock
- Active extrapulmonary or disseminated infection
- Active tuberculosis infection
- HIV infection with detectable viral load
- Limited functional status (e.g. non-ambulatory) with poor potential for post-transplant rehabilitation
- Progressive cognitive impairment
- Repeated episodes of non-adherence without evidence of improvement (Note: For pediatric members this is not an absolute contraindication and ongoing assessment of non-adherence should occur as they progress through different developmental stages)
- Active substance use or dependence including current tobacco use, vaping, marijuana smoking, or IV drug use
- Other severe uncontrolled medical condition expected to limit survival after transplant

## CODING AND STANDARDS

### Codes

Code	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 prepare pulmonary venous/atrial cuff, pulmonary artery, and bronchus; unilateral
32856	Backbench standard preparation of cadaver donor lung allograft prior to transplantation, including dissection of allograft from surrounding soft

Code	Description
	tissues to prepare pulmonary venous/atrial cuff, pulmonary artery, and bronchus; bilateral
S2060	Lobar lung transplantation
S2061	Donor lobectomy (lung) for transplantation, living donor
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 posttransplant care in the global definition

## Applicable Lines of Business

<input type="checkbox"/>	CHIP (Children’s Health Insurance Program)
<input type="checkbox"/>	Commercial
<input type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input type="checkbox"/>	Medicare Advantage

## BACKGROUND

A list of medical conditions treated by lung transplantation may include:

- Pulmonary vascular disease:
  - Primary pulmonary hypertension
  - Eisenmenger’s syndrome or complex
  - Pulmonary hypertension secondary to thromboembolic disease
  - Cardiomyopathy with pulmonary hypertension
- Obstructive lung disease:
  - Emphysema – idiopathic
  - Emphysema – alpha (1) antitrypsin deficiency
  - Cystic Fibrosis

- Bronchiectasis
- Chronic Obstructive Pulmonary Disease (COPD)
- Restrictive lung disease:
  - Idiopathic pulmonary fibrosis
  - Interstitial pulmonary fibrosis
  - Sarcoidosis
  - Asbestosis
- Subsequent operation for failure of original graft

## European Pediatric Pulmonary Vascular Disease Network Risk Stratification <sup>(7)</sup>

- EPPVDN Pediatric Pulmonary Hypertension Risk Score Calculator
- High risk factors in pediatric pulmonary hypertension and suspected pulmonary hypertensive vascular disease:
  - Clinical evidence of right ventricle (RV) failure
  - Progression of symptoms
  - Presence of syncope
  - Failure to thrive
  - WHO functional class III-IV
  - Elevated serum NT-proBNP
  - Cardiac imaging shows signs of:
    - Severe RA/RV enlargement
    - RV systolic dysfunction
    - RV/LV end-systolic ratio > 1.5 (PSAX)
    - Decreased tricuspid annular plane systolic excursion (TAPSE)
    - Systolic/diastolic (S/D) ratio > 1.4
    - Pulmonary artery acceleration time by transthoracic Doppler echocardiography (PAAT) < 70 ms
    - Pericardial effusion
  - Invasive hemodynamics shows:
    - Cardiac Index (CI) < 2.5 l/min/m<sup>2</sup>
    - Mean right atrial pressure (mRAP) > 15 mmHg
    - Mean pulmonary artery pressure (mPAP)/mean systemic artery pressure (mSAP) > 0.75

- Pulmonary vascular resistance index (PVRI) > 15 WU.m2

## **BODE Index for COPD Survival Prediction (8)**

- FEV1% Predicted After Bronchodialator
  - ≥ 65% (0 points)
  - 50-64% (1 point)
  - 36-49% (2 points)
  - ≤ 35% (3 points)
- 6-Minute Walk Distance
  - ≥ 350 Meters (0 points)
  - 250-349 Meters (1 point)
  - 150-249 Meters (2 points)
  - ≤ 149 Meters (3 points)
- Modified Medical Research Council Scale (MMRC) Dyspnea Scale
  - MMRC 0: Dyspneic on strenuous exercise (0 points)
  - MMRC 1: Dyspneic on walking a slight hill (0 points)
  - MMRC 2: Dyspneic on walking level ground; must stop occasionally due to breathlessness (1 point)
  - MMRC 3: Must stop for breathlessness after walking 100 yards or after a few minutes (2 points)
  - MMRC 4: Cannot leave house; breathless on dressing/undressing (3 points)
- Body Mass Index
  - > 21 (0 points)
  - ≤ 21 (1 point)
- Approximate 4 Year Survival Interpretation:
  - 0-2 Points: 80%, 3-4 Points: 67%, 5-6 points: 57%, 7-10 points: 18%

## **Comprehensive Risk Assessment in PAH (2)**

Low Risk (< 5%)

- Absent signs of right heart failure (HF)
- No progression of symptoms and clinical manifestations
- No syncope
- WHO functional class I-II
- 6-minute walking distance (6MWD) > 440 m

- Cardiopulmonary exercise testing:
  - Peak VO<sub>2</sub> > 15 mL/min/kg (> 65% predicted)
  - Ventilatory equivalents for carbon dioxide/oxygen uptake (VE/VCO<sub>2</sub>) slope < 36
- Brain natriuretic peptide (BNP) < 50 ng/L
- N-terminal pro-brain natriuretic peptide (NT-proBNP) < 300 ng/L
- Echocardiography:
  - Right atrium (RA) area < 18 cm<sup>2</sup>
  - Tricuspid annular plane systolic excursion/systolic pulmonary arterial pressure (TAPSE/sPAP) > 0.32 mm/mmHg
  - No pericardial effusion
- Cardiac MRI:
  - Right ventricular ejection fraction (RVEF) > 54%
  - Stroke volume index (SVI) > 40 mL/m<sup>2</sup>
  - Right ventricular end-systolic volume index (RVESVI) < 42 mL/m<sup>2</sup>
- Hemodynamics:
  - Right atrial pressure (RAP) < 8 mmHg
  - Cardiac index (CI) ≥ 2.5 L/min/m<sup>2</sup>
  - SVI > 38 mL/m<sup>2</sup>
  - Mixed venous oxygen saturation (SvO<sub>2</sub>) > 65%

#### Intermediate Risk (5-20%)

- Absent signs of right HF
- Slow progression of symptoms and clinical manifestations
- Occasional syncope
- WHO functional class III
- 6MWD between 165-440 m
- Cardiopulmonary exercise testing:
  - Peak VO<sub>2</sub>: 11 - 15 mL/min/kg (35-65% predicted)
  - VE/VCO<sub>2</sub> slope: 36-44
- BNP: 50-800 ng/L
- NT-proBNP: 300-1100 ng/L
- Echocardiography:
  - RA area: 18-26 cm<sup>2</sup>

- TAPSE/sPAP: 0.19-0.32 mm/mmHg
- Minimal pericardial effusion
- Cardiac MRI:
  - RVEF: 37-54%
  - SVI: 26-40 mL/m<sup>2</sup>
  - RVESVI: 42-54 mL/m<sup>2</sup>
- Hemodynamics:
  - RAP: 8-14 mmHg
  - CI: 2.0-2.4 L/min/m<sup>2</sup>
  - SVI: 31-38 mL/m<sup>2</sup>
  - SvO<sub>2</sub>: 60-65%

High Risk (>20%)

- Present signs of right HF
- Rapid progression of symptoms and clinical manifestations
- Repeated syncope
- WHO functional class IV
- 6MWD < 165 m
- Cardiopulmonary exercise testing:
  - Peak VO<sub>2</sub> < 11 mL/min/kg (< 35% predicted)
  - VE/VCO<sub>2</sub> slope > 44
- BNP > 800 ng/L
- NT-proBNP > 1100 ng/L
- Echocardiography:
  - RA area > 26 cm<sup>2</sup>
  - TAPSE/sPAP < 0.19 mm/mmHg
  - Moderate or large pericardial effusion
- Cardiac MRI:
  - RVEF < 37%
  - SVI < 26 mL/m<sup>2</sup>
  - RVESVI > 54 mL/m<sup>2</sup>
- Hemodynamics:
  - RAP > 14 mmHg

- CI < 2.0 L/min/m<sup>2</sup>
- SVI < 31 mL/m<sup>2</sup>
- SvO<sub>2</sub> < 60%

## New York Heart Association (NYHA) Functional Classification for Heart Failure

The New York Heart Association (NYHA) classes of heart failure is the most commonly used system to classify stages of heart failure. <sup>(9)</sup> Classes are based on physical activity limitations.

- Class I: No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, heart palpitation, dyspnea or shortness of breath
- Class II: Slight limitation of physical activity. Comfortable at rest, but ordinary physical activity results in fatigue, heart palpitation, shortness of breath or chest pain
- Class III: Marked limitation of physical activity. Comfortable at rest, but less than ordinary activity causes fatigue, heart palpitation, shortness of breath or chest pain
- Class IV: Symptoms of heart failure at rest. Any physical activity increases discomfort

## POLICY HISTORY

Date	Summary
May 21, 2026	<ul style="list-style-type: none"> <li>● Annual Review - Replaced patient with member throughout; updated indications under General Criteria for Lung and Lobar Lung Transplant; updated title of Obstructive Pulmonary Diseases section to include Chronic and spelled out BODE in indications; minor update under Cystic Fibrosis and other causes of Bronchiectasis; minor update under High Risk Factors with Unfavorable Implications section; updated description of procedure codes 32851, 32851, 32853, 32854, 32855, 32856 and S2060; updates to European Pediatric Pulmonary Vascular Disease Network section; shortened the title of the Body Mass Index, Airflow Obstruction, Dyspnea and Exercise Capacity section; minor update to the Comprehensive Risk Assessment in PAH section; updated the New York Heart Association Functional Classification section; updated References</li> </ul>
November 20, 2025	<ul style="list-style-type: none"> <li>● This guideline replaces PA.007.CC Transplant: Lung and Lobar Lung</li> <li>● Editorial changes to match the formatting and layout of the new template, no changes to clinical content</li> </ul>



## **LEGAL AND COMPLIANCE**

### **Guideline Approval**

#### **Committee**

**Reviewed / Approved by Evolent Administrative Services Medical Policy Committee**

#### **Disclaimer**

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