

# Ontario's Adult Listing Criteria for Lung Transplantation

Version 4.0



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# Ontario's Adult Listing Criteria for Lung Transplantation

## PATIENT LISTING INDICATIONS

Each patient is assessed individually for their suitability for transplantation by the transplant program. The criteria identified below are the conditions for which a patient may be eligible to be waitlisted for lung transplantation in Ontario.

- 1) Chronic Obstructive Pulmonary Disease (COPD):** Listing for lung transplantation may be considered for patients with COPD. Such patients would meet the following criteria:
  - BODE index 7-10;
  - Additional factors that may prompt listing include:
    - FEV1 <20% predicted;
    - History of severe exacerbations
    - Presence of moderate to severe pulmonary hypertension;
    - Chronic hypercapnia
- 2) Cystic Fibrosis and Other Causes of Bronchiectasis:** Listing for lung transplantation should occur for an individual with cystic fibrosis meeting any of the above referral criteria in combination with any of the following:
  - FEV1 <25% predicted;
  - 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 (PA systolic pressure >50 mmHg on echocardiogram or evidence of RV dysfunction);
  - Frequent hospitalization, particularly if >28 days hospitalized in the preceding year;
  - Worsening nutritional status particularly with BMI <18 kg/m<sup>2</sup> despite nutritional interventions;
  - Recurrent massive hemoptysis despite bronchial artery embolization;
  - Rapid lung function decline or progressive symptoms (>30% relative decline in FEV1 over 12 months);
  - World Health Organization Functional Class IV.
- 3) Interstitial Lung Disease:** Listing for lung transplantation may be considered for patients with interstitial lung disease (ILD). Such patients would have:
  - Any form of pulmonary fibrosis with one of the following in the past 6 months despite of appropriate treatment:
    - Absolute decline in 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 distance in the past 6 months;
  - Pulmonary hypertension on right heart catheterization or 2-dimensional echocardiography (in the absence of diastolic dysfunction); or,
  - Hospitalization because of respiratory decline, pneumothorax, or acute exacerbation.

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- 4) Pulmonary Arterial Hypertension:** Listing for lung transplantation may be considered for patients with pulmonary arterial hypertension. Such patients would have one of the following:
- Life-threatening hemoptysis
  - Progressive, but not end-stage liver or kidney dysfunction due to PAH
  - ESC/ERS high risk of REAVEL risk score >10 on appropriate PAH therapy, including IV or SC prostacyclin analogues
  - Progressive hypoxemia, especially in patients with PVOD or PCH
- 5) Sarcoidosis:** Listing for lung transplantation may be considered for patients with sarcoidosis. Such patients would meet the following criteria:
- Impairment of exercise tolerance (NYHA functional class III or IV) and any of the following:
    - Hypoxemia at rest;
    - Pulmonary hypertension; or,
    - Elevated right atrial pressure exceeding 15 mm Hg.
- 6) Lymphangioleio-myomatosis (LAM):** 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.

NOTE: 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 patients on the waiting list.

- 7) Pulmonary Langerhans Cell Histiocytosis (Eosinophilic Granuloma):** Patients with pulmonary Langerhans cell histiocytosis may be considered for lung transplantation. Such patients would have one of the following:
- Severe impairment in lung function and exercise capacity; or,
  - Hypoxemia at rest.
- 8) General:** Patients not included in the preceding categories but have a poor quality of life (based on the clinical judgment of the care team at the time of assessment) may be considered for lung transplantation. Listing for lung transplantation may also be considered for patients if the following requirements are met:
- The absence of obvious contraindications for transplant; and,
  - The potential to undergo rehabilitation after transplantation.
- 9) Lack of Alternative Medical Options:** Patients who fail to respond to maximal medical therapy or the absence of alternative/conventional surgical options may be considered for lung transplantation.

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## **ABSOLUTE LISTING CONTRAINDICATIONS**

The following are conditions relating to the lung transplant candidate that constitute absolute contraindications to lung transplantation. As such, they prevent a transplant from being done until the condition is resolved.

- 1) **Psychosocial Issues:** Patients must undergo a complete psychosocial evaluation prior to listing for transplantation. Patients who display the following are not candidates for lung transplantation:
  - Repeated episodes of non-adherence to medical therapy without evidence of improvement
  - Active substance abuse or dependence including current tobacco use, vaping, marijuana smoking or IV drug use
- 2) **Infections:** Patients with active tuberculosis (TB) infection, active extrapulmonary or disseminated infection and HIV infection with detectable viral load are not candidates for transplantation.
- 3) **Consent:** Patients who do not want a transplant should not be listed for lung transplantation. Patients who are unable to give informed consent and do not have a substitute decision maker available, resulting in an inadequate or unsafe care plan post-transplant, are not candidates for lung transplantation.
- 4) **Medical Stability:** Patients with the following acute medical instability and/or with severe uncontrolled medical condition expected to limit survival after transplant are not candidates for lung transplantation:
  - Glomerular Filtration Rate (GFR) <40 mL/min/1.73m<sup>2</sup>; or
  - Acute renal failure with rising creatinine or on dialysis and low likelihood of recovery; or
  - Acute Coronary Syndrome or Myocardial infarction within 30 days (excluding demand ischemia); or
  - Liver cirrhosis with portal hypertension or synthetic dysfunction unless being considered for multi-organ transplant; or
  - Acute Liver Failure; or
  - Septic shock
- 5) **Stroke:** Patients who experienced stroke within 30 days are not candidates for lung transplantation
- 6) **Malignancy:** Patients who have active malignancy with high risk of recurrence or death related to cancer are not candidates for lung transplantation.
- 7) **Functional Status:** Patients with limited functional status (e.g. non-ambulatory) with poor potential for post-transplant rehabilitation and/or with progressive cognitive impairment are not candidates for transplantation.

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## **RELATIVE LISTING CONTRAINDICATIONS:**

The following are conditions relating to the lung transplant candidate that constitute relative contraindications to lung transplantation, with **high or substantially increased risk factors** and at **low risk factors**. Candidates with *high or substantially increased risk factors* may be considered for lung transplantation in centers with expertise specific to the condition. Modifiable conditions should be optimized when possible. Candidates with *low risk factors* may result in unfavorable implications for short and/or long-term outcomes after lung transplant. While each patient is evaluated on an individual basis, the presence of one or more of the following may preclude a candidate from being listed on the lung transplantation wait list.

### **1) Age:**

- **High Risk:** Patients older than 70 years old may have high risk for lung transplantation.
- **Low Risk:** Patients who are 65-70 years old may have low risk for lung transplantation.

### **2) Functional Status:**

- **High Risk:** Patients with limited functional status with potential for post-transplant rehabilitation may have high risk for lung transplantation.
- **Low Risk:** Patients with frailty (i.e. a generalized vulnerability to stressors resulting from the presence of multiple physiologic deficits) may have low risk for lung transplantation.

### **3) Infection:**

- **High Risk:** Patients with the following infections may have high risk for lung transplantation:
  - *Lomentospora prolificans* infection
  - Hepatitis B and/or C infections with detectable viral load and liver fibrosis
  - *Burkholderia cenocepacia*, *Burkholderia gladioli*
  - *Mycobacterium abscessus* infection
- **Low risk:** Patients with *Scedosporium apiospermum* infection and HIV infections with undetectable viral load may have low risk for lung transplantation.

### **4) Hematologic Abnormalities:**

- **High Risk:** Patients with untreatable hematologic disorders including bleeding diathesis, thrombophilia, or severe bone marrow dysfunction may have high risk for lung transplantation.
- **Low Risk:** Patients with thrombocytopenia, leukopenia, or anemia with high likelihood of persistence after transplant may have low risk for lung transplantation.

### **5) Body Mass Index (BMI):**

- **High Risk:** Patients with BMI  $\geq 35\text{kg/m}^2$  or BMI  $< 16\text{kg/m}^2$  may have high risk for lung transplantation.
- **Low Risk:** Patients with class I obesity (BMI 30-34.9  $\text{kg/m}^2$ ) or underweight (BMI 16-17 $\text{kg/m}^2$ ) may have low risk for lung transplantation.

### **6) Osteoporosis (Low Risk):** Patients with severe or symptomatic osteoporosis may have low risk for lung transplantation.

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## 7) Extracorporeal Life Support/ Mechanical Ventilation:

- **High Risk:** Patients with extracorporeal life support (ECLS) may have high risk for lung transplantation.
- **Low Risk:** Patients with mechanical ventilation may have low risk for lung transplantation.

## 8) Disease:

- **High Risk:** Patients with untreatable advanced dysfunction of another major organ system (e.g. heart, liver, or kidney) may have high risk for lung transplantation unless combined organ transplantation can be performed. Patients with severe coronary artery disease that requires coronary artery bypass grafting at transplant or reduced left ventricular ejection fraction <40% may not be eligible for lung transplantation.

Other medical conditions that have not resulted in end-stage organ damage, such as significant cerebrovascular disease and esophageal dysmotility should be optimally treated before transplantation.

- **Low Risk:** Patients with hypoalbuminemia, GFR at 40-60mL/min/1.73m<sup>2</sup>, mild to moderate coronary artery disease, or severe coronary artery disease that can be revascularized via percutaneous coronary intervention prior to transplant may have low risk for lung transplantation. Patients with prior coronary artery bypass grafting (CABG) or with reduced left ventricular ejection fraction 40-50% may have low risk for lung transplantation.

Other medical conditions that have not resulted in end-stage organ damage, such as diabetes mellitus that is poorly controlled), esophageal dysmotility, peripheral vascular disease, connective tissue diseases (including scleroderma, lupus, inflammatory myopathies), or severe gastroesophageal reflux may have low risk for lung transplantation.

## 9) Deformity (High Risk):

Patients with chest wall or spinal deformity expected to cause restriction after transplant have high risk for lung transplantation.

## 10) Lung Re-Transplantation:

- **High Risk:** Patients with the following condition(s) may have high risk for lung transplantation:
  - Re-Transplant <1 year following initial lung transplant
  - Re-Transplant for restrictive chronic lung allograft dysfunction (CLAD)
  - Re-Transplant for AMR as etiology for CLAD
- **Low Risk:** Patients who require re-transplant >1 year for obstructive CLAD may have low risk for lung transplantation.

## 11) Psychosocial Issues (High Risk):

Patients who display the following may have high risk for lung transplantation:

- Psychiatric, cognitive or psychological conditions with potential to interfere with medical adherence without sufficient support systems

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- Absence of adequate/reliable social support system or caregiving plan; or,
  - Lack of understanding of disease and/or transplant despite teaching

**12) Edible Marijuana Use (Low Risk):** Patients who have edible marijuana use may have low risk eligible for lung transplantation.

**13) Malnutrition:** Patients with progressive or severe malnutrition may not be eligible for lung transplantation.

**14) Chest surgery and Pleurodesis (Low Risk):** Patients with extensive prior chest surgery and/or prior pleurodesis may have low risk for lung transplantation.

**15) COVID-19 Vaccination:** All patients medically eligible for COVID-19 vaccination are highly recommended to be up-to-date as per ministry guidelines against COVID-19, before being considered for lung transplantation. This includes patients who are currently listed for lung transplantation and prospective patients undergoing lung transplant evaluation.

- Transplant will be considered on a case-by-case basis, considering medical urgency and an evaluation of risks to the patient in the context of Lung transplant.

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## Version Control

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<b>Version 1.0</b>	Created May 2011
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