Patient Referral Guidelines
Heart/Lung Transplant

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Criteria
For Medicare Members

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<tr>
<td>CMS Coverage Manuals</td>
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<tr>
<td>National Coverage Determinations (NCD)</td>
<td>Heart Transplants (260.9)</td>
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<tr>
<td>Local Coverage Determinations (LCD)</td>
<td>None</td>
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For Non-Medicare Members
Heart Transplant

Transplantation may be considered for patients with end-stage or life-threatening disease who have no prospect for prolonged survival, or whose quality of life is severely impaired. The following are current, generally accepted guidelines for Heart transplantation. These guidelines for referral for transplant evaluation are not intended as an automatic inclusion or exclusion of a candidate for referral. As such, these should be applied together with careful clinical judgment.

1. GENERAL PRINCIPLES
   1.1. If clinical parameters of end-stage or life-threatening disease indicate the need for transplantation, then early referral should be made.
   1.2. Patients with a history of malignancy with a moderate to high risk of recurrence (as determined after consultation with oncologist considering tumor type, response to therapy, and presence or absence of metastatic disease) may be unsuitable candidates for transplantation. Patients with low risk of recurrence may be considered.
   1.3. Uncontrollable infection is a contraindication to transplant.
   1.4. Candidates with a history of substance abuse must be free from alcohol and other substance abuse for six (6) months and have been evaluated by a substance abuse program. The risk of recidivism, which has been documented to negatively impact transplant outcomes, must be addressed and considered to be low ii, iii, iv. Exceptions may be made on a case-by-case basis.
   1.5. Candidates for thoracic organ (heart, lung and heart/lung) transplants must be free from tobacco use for the previous six (6) months. Routine monitoring may be required. Specific programs for abdominal organs (liver, intestines and kidney) may require abstinence from tobacco products to be actively listed.
   1.6. Candidates must have adequate social support systems and display a proven record of adherence to medical treatment.
       1.6.1. Patient must have a care giver or care givers who are physically and cognitively able to assist the patient with self-care activities and are available to travel within short notice to the KP approved transplant Center of Excellence.
   1.7. Evidence of non-adherence may be failure to keep appointments, failure to make steady progress in completing pre-transplant evaluation requirements, failure to accurately follow medication regimens or failure to accomplish the activities required for maintenance on the waiting list. Patients must be willing and able to travel within short notice to the KP approved transplant Center of Excellence and, if necessary, return for treatment of complications.
1.8. The presence of significant irreversible neurologic dysfunction, active psychological and/or psychiatric conditions, and/or other social behaviors that prevent adherence with a complex medical regimen, are considered contraindications for referral for transplant.

1.9. Whenever transplant is considered as an option and discussed with the patient and/or family, consultation with Advanced Life Care Planning/Palliative Care resources is strongly recommended.

2. INDICATIONS FOR HEART TRANSPLANT

2.1. End-stage heart disease as evidenced by one or more of the following:

2.1.1. Functional class III or IV

2.1.2. Not correctable by medical or other surgical therapies

2.1.3. A low VO2 maximum:

\[ \text{VO2 maximum} \leq 14 \text{ ml/kg/min in patients not on a beta blocker} \]

\[ \text{VO2 maximum} \leq 12 \text{ ml/kg/min in patients on a beta blocker} \]

\[ \text{VO2 maximum} < 19 \text{ ml/kg/min adjusted for lean body mass in patients with a BMI > 30 kg/m}^2 \]

\[ \text{VO2 maximum} \text{ less than 50% of age predicted maximum.} \]

2.1.4. A VE/VCO2 > 35 in a patient with a sub-maximal cardiopulmonary exercise test (RER < 1.05)²

2.1.5. Cardiac index < 2 L/min/m²

2.2. Unable to wean from mechanical or inotropic support.

2.3. Amyloid Cardiomyopathy

2.3.1. TTR Amyloid

2.3.2. (AL) Amyloidosis without significant extra-cardiac involvement.

2.4. Refractory Life-Threatening Arrhythmias

3. The transplant should only be offered for conditions in which cardiac transplant has proven clinical benefits. CONTRAINDICATIONS FOR HEART TRANSPLANT (In conjunction with the General Principles listed above in Section 1 of these guidelines):

3.1. Significant diseases such as:

3.1.1. Severe uncontrolled or poorly controlled hypertension.

3.1.2. Clinically significant vascular disease not correctable by intervention.

3.1.3. Pulmonary hypertension not reversible by drug manipulation despite maximum tolerated medical management. vii

3.1.3.1. Adults: PVR > 4-6 Wood units or transpulmonary gradient > 15 mm Hg

3.1.3.2. Children: PVR > 9 Wood units

3.1.4. Severe pulmonary disease after optimal treatment of severe heart failure. viii

3.1.5. Severe hepatic disease after optimal treatment of severe heart failure. viii

3.1.6. Kidney disease with creatinine clearance < 34 ml/kg/min or GFR < 30 ml/min after optimal treatment of heart failure. viii, ix, x

3.1.7. Active and/or progressive central nervous system disease excluding patients with embolic stroke who have recovered completely.

3.1.8. Evidence of cachexia or malnutrition (BMI < 19 kg/m² or < 80% ideal body weight). x

3.1.9. Obesity (BMI > 35 kg/m² or > 140% ideal body weight) x has been associated with poor outcomes after cardiac transplant.

3.1.10. Diabetes with complications resulting in severe end-organ damage.

3.1.11. Auto/acquired immune disease with multi-organ manifestation

3.1.12. Acute pulmonary embolus

3.1.13. Active peptic ulcer disease

3.1.14. Severe symptomatic osteoporosis

3.1.15. Age over 70 (Carefully selected patients over 70 years of age may be considered for cardiac transplantation)

3.1.16. AL Amyloidosis with significant extra-cardiac manifestations

3.1.17. Patients with viral hepatitis will require additional evaluation, including hepatology consultation.

3.1.18. Any other co-morbid condition that would limit life expectancy or quality of life.


ii Selected patients for combined organ transplant will be evaluated on a case-by-case basis.

iii Must have 20mg per kilogram of creatinine in a 24-hour collection period. Creatinine clearance can also be calculated by the Cockcroft-Gault formula.


Body Mass Index (BMI) = (weight [kg] / height² [m²]). Percent Ideal Body Weight (PIBW) was calculated as follows: Men IBW = 106 pounds for the
LUNG TRANSPLANT:

Transplantation may be considered for patients with end-stage or life-threatening disease who have no prospect for prolonged survival, or whose quality of life is severely impaired. The following are current, generally accepted, guidelines for lung & heart/lung transplantation. These guidelines for referral for transplant evaluation are not intended as an automatic inclusion or exclusion of a candidate for referral. As such, these should be applied together with careful clinical judgment.

1. GENERAL PRINCIPLES

1.1. If clinical parameters of end-stage or life-threatening disease indicate the need for transplantation, then early referral should be made.

1.2. Patients with a history of malignancy with a moderate to high risk of recurrence (as determined after consultation with oncologist considering tumor type, response to therapy, and presence or absence of metastatic disease) may be unsuitable candidates for transplantation. Patients with low risk of recurrence may be considered.

1.3. Uncontrollable infection is a contraindication to transplant.

1.4. Candidates with a history of substance abuse must be free from alcohol and other substance abuse for six (6) months and have been evaluated by a substance abuse program. The risk of recidivism, which has been documented to negatively impact transplant outcomes, must be addressed and considered to be low. Exceptions may be made on a case-by-case basis.

1.5. Candidates for thoracic organ (heart, lung and heart/lung) transplants must be free from tobacco use for the previous six (6) months. Routine monitoring may be required. Specific programs for abdominal organs (liver, intestines, and kidney) may require abstinence from tobacco products in order to be actively listed.

1.6. Candidates must have adequate social support systems and display a proven record of adherence to medical treatment.

1.6.1. Patients must have a caregiver or caregivers who are physically and cognitively able to assist the patient with self-care activities and are available to travel within short notice to the KP approved transplant Center of Excellence.

1.6.2. Evidence of non-adherence may be failure to keep appointments, failure to make steady progress in completing pre-transplant evaluation requirements, failure to accurately follow medication regimens or failure to accomplish the activities required for maintenance on the waiting list.

1.7. Patients must be willing and able to travel within short notice to the KP approved transplant Center of Excellence and, if necessary, return for treatment of complications.

1.8. The presence of significant irreversible neurologic dysfunction, active psychological and/or psychiatric conditions, and/or other social behaviors that prevent adherence with a complex medical regimen, are considered contraindications for referral for transplant.

1.8.1. Evidence of such non-adherence may be: failure to keep appointments, failure to make steady progress in completing pre-transplant evaluation requirements, failure to accurately follow medication regimens or failure to accomplish the activities required for maintenance on the waiting list.

1.9. Whenever transplant is considered as an option and discussed with the patient and/or family, consultation with Advanced Life Care Planning/Palliative Care resources is strongly recommended.

2. INDICATIONS FOR LUNG TRANSPLANT

2.1. A disease state in which transplantation has become an accepted mode of treatment worldwide.

2.2. Patients should be referred by a pulmonologist or a cardiologist who has accumulated data that defines a disease potentially treatable by transplantation and that said disease is progressing despite maximal medical therapy.
2.3. Patient should be ambulatory with rehabilitation potential.

3. CONTRAINDICATIONS FOR LUNG TRANSPLANT

3.1. Invasive mechanical ventilator support vii.
3.2. Unresolved infection (except in cystic fibrosis and bronchiectasis).
3.3. Other systemic diseases including but not limited to:
   3.3.1. Diabetes with end organ effects; i.e., renal, cardiac or uncorrectable peripheral vascular disease. Insulin use itself is not a contraindication.
   3.3.2. Uncontrolled hypertension.
   3.3.3. Significant neurologic disease impairing cognitive function.
   3.3.4. Malnutrition viii
   3.3.5. Obesity >140% ideal body weight or BMI >32 kg/m² ix, x (with an understanding that a BMI <30 may be necessary for transplantation).
   3.3.5.1. May wish to consider initiating transplant workup if patient has pulmonary fibrosis and BMI >32 (but <34) if showing willingness to lose weight.
   3.3.6. Advanced hepatic dysfunction.
   3.3.7. Advanced renal dysfunction (creatinine clearance < 50 ml/min. after maximum therapy). However, patients with underlying cardiopulmonary causes of low creatinine clearance can be considered for transplant on a case-by-case basis.
   3.3.8. Evidence of clinically significant obstructive coronary artery disease and/or LVEF <40%. xi
   3.3.9. Active or unresolved peptic ulcer disease.
   3.3.10. Chronic opiate use: Patients should be seen by a pain management specialist for alternative forms of therapy.
   3.3.11. Uncorrectable bleeding diathesis or clotting disorder

4. RELATIVE CONTRAINDICATIONS

4.1. Patients with previous thoracotomy and/or sclerosing procedures should be considered on a case by case basis.
4.2. Systemic corticosteroid therapy >10 mgs prednisone daily.
4.3. Esophageal dysmotility and reflux. Surgical repair may be necessary xii
4.4. Age >70 for lung transplant referral.
4.5. Symptomatic osteoporosis.
4.6. Major mechanical chest deformity (such as kyphoscoliosis).

PATIENT PROFILE FOR COMMON DIAGNOSES LUNG TRANSPLANT REFERRAL GUIDELINES

Any or all of the listed guidelines for each disease entity should raise consideration for lung transplantation evaluation. Clinical correlation is always of primary importance.

1. GROUP A – Obstructive Lung Disease xiii, xiv (See Table 1 Below)
   1.1. FEV1 < 25 %
   1.2. DLCO < 40%
   1.3. Hypoxemia; PO2 < 55
   1.4. Hypercapnia; PCO2 > 51
   1.5. Bode Index > 5xv

2. GROUP B – Pulmonary Arterial Hypertension (See Table 1 Below)
   2.1. Patients with clinically significant PAH should be evaluated by physicians experienced in treating pulmonary hypertension and have received maximum available pharmacological treatment.
   2.2. Possible indications for referral include
      2.1.1. Pericardial Effusionvi
      2.1.2. World Health Organization (WHO) (New York Heart Association) class 3 or 4
      2.1.3. Lack of improvement in WHO Class 3 or 4 and/or lack of improvement in 6-minute walk test of < 350 meters, despite maximum pharmacological therapy.
   2.2. Definite indications, after maximum pharmacologic treatment for referral include: xx
      2.2.1. Mean RA > 15 mmHg
      2.2.2. Cardiac Index < 2L per minute. Untreated, the mean survival for patients with these criteria is 10-11 months.
3. **GROUP C – Cystic Fibrosis** xxix (See table 1 Below)
   3.1. FEV1 < 40%
   3.2. PO2 < 55
   3.3. Clinical deterioration, especially in young female patients, as characterized by increasing number of hospitalizations, including recurrent pneumothoraces, rapid fall of FEV1, recurrent major hemoptysis uncontrolled by embolization and/or increasing cachexia should prompt consideration for transplant referral.
   3.4. PCO2 > 51
   3.5. Patients with *Burkholderia cepacia* have a relative contraindication.

4. **GROUP D – Restrictive Lung Disease** xxix, xxx (See Table 1 Below)
   4.1. Force Vital Capacity < 80%xxix
   4.2. Decline in Forced Vital Capacity of ≥10% and/or decline in DLCO ≥ 15% during 6 months of follow-up xxix
   4.3. Diffusing Capacity (corrected for alveolar volume) < 60%
   4.4. Evidence of interstitial lung disease on HRCT in conjunction with one or more of the above.

**Lung transplant should be considered when a definitive diagnosis of usual interstitial pneumonitis (UIP) or idiopathic pulmonary fibrosis (IPF) is made and may be considered for the diagnosis of fibrotic nonspecific interstitial pneumonitis (NSIP).**

**OTHER CONDITIONS**

Other conditions for which transplant may be appropriate include the Lung diseases described in Table 1 below.xxxi

**Table 1:** Lung allocation score (LAS) primary diagnostic groupings for lung transplant candidates

<table>
<thead>
<tr>
<th>LAS lung disease diagnosis grouping</th>
<th>Conditions</th>
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<tbody>
<tr>
<td><strong>Group A</strong> (obstructive lung disease)</td>
<td>Chronic obstructive pulmonary disease (COPD), with or without alpha-1-antitrypsin deficiency, due to chronic bronchitis and or emphysema</td>
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<tr>
<td></td>
<td>Lymphangioleiomyomatosis (LAM)</td>
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<tr>
<td></td>
<td>Bronchiectasis, including primary ciliary dyskinesia</td>
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<tr>
<td></td>
<td>Sarcoidosis with a mean pulmonary artery (PA) pressure ≤30 mmHg</td>
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<tr>
<td><strong>Group B</strong> (pulmonary vascular disease)</td>
<td>Idiopathic pulmonary arterial hypertension (IPAH, formerly known as primary pulmonary hypertension (PPH))</td>
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<tr>
<td></td>
<td>Eisenmenger’s syndrome</td>
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<tr>
<td></td>
<td>Other pulmonary vascular diseases</td>
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<tr>
<td></td>
<td>Cystic fibrosis (CF)</td>
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<tr>
<td><strong>Group C</strong> (cystic fibrosis or immunodeficiency disorders)</td>
<td>Immunodeficiency disorders such as hypogammaglobulinemia</td>
</tr>
<tr>
<td><strong>Group D</strong> (restrictive lung disease)</td>
<td>Idiopathic pulmonary fibrosis (IPF)</td>
</tr>
<tr>
<td></td>
<td>Pulmonary fibrosis due to other causes</td>
</tr>
<tr>
<td></td>
<td>Sarcoidosis with mean PA pressure &gt;30 mmHg</td>
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<tr>
<td></td>
<td>Obliterative bronchiolitis (nonretransplant)</td>
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Source: Revision to policy 3.7.6.1.

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See Addendum 1, New system for lung allocation (enclosed)


Liver Transplantation 2006, 12:813-820. Alcohol consumption patterns and predictors of use following liver transplantation for alcoholic liver disease.


Under acceptable case-by-case circumstances, a patient who has been listed for a lung transplant and previously ambulatory, and now requires mechanical ventilation, may still be a potential candidate for lung transplantation. Patients who have been listed for lung transplant, and require invasive mechanical ventilation, can remain on the transplant list provided that there remains rehabilitation potential. On a carefully selected case-by-case basis, patients who are on invasive mechanical support, and are ambulatory with a potential for rehabilitation, can be listed for lung transplant. *Chest* 2001; 119(1):224-227.

Any disorder of nutrition causing a lack of necessary or proper food substances in the body or improper absorption and distribution of them (Taber’s Cyclopedic Medical Dictionary).

Journal of Heart and Lung Transplantation Vol. 18 (8), August 1999, pg 750-761
Background
This service is covered when it is medically necessary and identified as a benefit in the consumer’s coverage contract. Kaiser Permanente adopted the MCG Guideline for medical necessity decision making.

Evidence and Source Documents
The scientific literature is periodically reviewed, and patient selection criteria are updated when new efficacy data becomes available.

Kaiser Permanente Committee on Medically Emerging Technology
Transplant, Lung, Double - 7/12/91 - Double lung transplantation is efficacious for appropriately selected patients.

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MDCRPC - Medical Director Clinical Review and Policy Committee
MPC - Medical Policy Committee

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<th>Revision History</th>
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<tr>
<td>03/05/2019</td>
<td>MPC approved to adopt KP National Criteria for Heart and Lung Transplant</td>
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<tr>
<td>09/03/2019</td>
<td>MPC approved to change General Principles 1.3 to <em>Uncontrollable infection is a contraindication to transplant</em> as recommended by KP National Transplant Services.</td>
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<td>03/03/2020</td>
<td>MPC approved the proposed changes from KP National Transplant Services</td>
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Codes
CPT: 33930, 33933, 33935, 33940, 33944, 33945