



Kaiser Foundation Health Plan of Washington

PATIENT REFERRAL GUIDELINES

Lung Transplant ^{i, ii, iii}

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Criteria

For Medicare Members

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, rather should be applied together with careful clinical judgment.

For Non-Medicare Members

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, rather should be applied together with careful clinical judgment.

1. GENERAL PRINCIPLES

- a. If clinical parameters of end-stage or life-threatening disease indicate the need for transplantation, early referral should be made.
- b. Patients with a history of malignancy with 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.
- c. Uncontrollable active infection is a contraindication to transplant.
- d. 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. [4.5.6](#) Exceptions may be made on a case-by-case basis.
- e. 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.
- f. Candidates must have adequate social support systems and display a proven record of adherence to medical treatment.
 - i. Patients 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.
 - ii. 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.

- g. 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.
- h. 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.
 - i. 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.
- i. 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

- a. Must meet all prerequisites listed in the General Principles section
- b. Any disease state in which transplantation has become an accepted mode of treatment worldwide including
 - i. Chronic obstructive pulmonary disease (COPD), which may include asthma, chronic bronchitis, emphysema and/or Alpha 1 antitrypsin deficiency
 - ii. Idiopathic pulmonary fibrosis
 - iii. Sarcoidosis
 - iv. Connective tissue disease-related pulmonary fibrosis
 - v. Eosinophilic granulomatosis
 - vi. Bronchiectasis
 - vii. Cystic fibrosis (CF)
 - viii. Pulmonary hypertension (both primary and secondary)
 - ix. Lymphangiomyomatosis (LAM)
 - x. Interstitial lung disease not otherwise defined.
- c. Patients should be referred for transplant evaluation by a pulmonologist or a cardiologist who has accumulated data defining both the disease as potentially treatable by transplantation and progression is occurring despite maximal medical therapy.
- d. Early referral is strongly encouraged for progressive lung disease with a poor prognosis⁷
- e. Ideally, the patient should be ambulatory with rehabilitation potential.

3. CONTRAINDICATIONS FOR LUNG TRANSPLANT

- a. Must meet all prerequisites listed in the General Principles section
- b. Invasive mechanical ventilator support⁸.
- c. Unresolved infection (except in cystic fibrosis and bronchiectasis).
- d. Uncontrolled chronic infection (i.e., HIV with detectable viral load)
- e. Other systemic diseases including but not limited to:
 - i. Diabetes with end organ effects; i.e., renal, cardiac or uncorrectable peripheral vascular disease. Insulin use itself is not a contraindication.
 - ii. Uncontrolled hypertension.
 - iii. Significant neurologic disease impairing cognitive function.
 - iv. Malnutrition⁹
 - v. Obesity >140% ideal body weight or BMI >32 kg/m² ^{10, 11}(with an understanding that a BMI <30 may be necessary for transplantation).
 - 1. May wish to consider initiating transplant workup if patient has pulmonary fibrosis and BMI >32 (but <34) if showing willingness to lose weight.
 - vi. Advanced hepatic dysfunction.
 - vii. 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.
 - viii. Evidence of clinically significant obstructive coronary artery disease and/or LVEF <40%. ¹²
 - ix. Active or unresolved peptic ulcer disease.
 - x. Chronic opiate use: Patients should be seen by a pain management specialist for alternative forms of therapy.
 - xi. Uncorrectable bleeding diathesis or clotting disorder

RELATIVE CONTRAINDICATIONS

- a. Patients with previous thoracotomy and/or sclerosing procedures should be considered on a case by case basis.

- b. Systemic corticosteroid therapy >10 mgs prednisone daily.
- c. Esophageal dysmotility and reflux. Surgical repair may be necessary.¹³
- d. Age >70 for lung transplant referral.
- e. Symptomatic osteoporosis.
- f. Major mechanical chest deformity (such as kyphoscoliosis).
- g. Short stature patients (in USA 4'11" for females and 5'4" for males) are significantly disadvantaged and early consideration of multiple listing is encouraged.

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 ^{14, 15} (See Table 1 Below)
 1. FEV1 < 25 %
 2. DLCO < 40%
 3. Hypoxemia; PO₂ < 55
 4. Hypercapnia; PCO₂ > 51¹⁶
 5. Bode Index > 5
2. GROUP B – Pulmonary Arterial Hypertension (See Table 1 Below)^{17, 18, 19}
 - a. Patients with clinically significant PAH should be evaluated by physicians experienced in treating pulmonary hypertension and have received maximum available pharmacological treatment.
 - b. Possible indications for referral include:
 - i. Pericardial Effusion²⁰
 - ii. World Health Organization (WHO) (New York Heart Association) class 3 or 4
 - iii. 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.
 - c. Definite indications, after maximum pharmacologic treatment for referral include: ²¹
 - i. Mean RA > 15 mmHg
 - ii. Cardiac Index < 2L per minute. Untreated, the mean survival for patients with these criteria is 10-11 months.

GROUP C – Cystic Fibrosis ²²(See table 1 Below)

- a. FEV1 < 40%
- b. PO₂ < 55
- c. Clinical deterioration, especially in young female patients, as characterized by increasing number of hospitalizations, including recurrent pneumothoraxes, rapid fall of FEV1, recurrent major hemoptysis uncontrolled by embolization and/or increasing cachexia should prompt consideration for transplant referral.
- d. PCO₂ > 51
- e. Patients with Burkholderia cepacia have a relative contraindication.

GROUP D – Restrictive Lung Disease) ^{22, 23}(See Table 1 Below)

- a. Force Vital Capacity < 80%²²
- b. Decline in Forced Vital Capacity of ≥10% and/or decline in DLCO ≥ 15% during 6 months of follow-up²²
- c. Diffusing Capacity (corrected for alveolar volume) < 60%
- d. Evidence of interstitial lung disease on HRCT in conjunction with one or more of the above.

Referral to lung transplant program 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.²⁴

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

LAS lung disease diagnosis grouping	
Group A (obstructive lung disease)	<ul style="list-style-type: none"> Chronic obstructive pulmonary disease (COPD), with or without alpha-1-antitrypsin deficiency, due to chronic bronchitis and or emphysema Lymphangioleiomyomatosis (LAM) Bronchiectasis, including primary ciliary dyskinesia Sarcoidosis with a mean pulmonary artery (PA) pressure ≤ 30 mmHg
Group B (pulmonary vascular disease)	<ul style="list-style-type: none"> Idiopathic pulmonary arterial hypertension (iPAH, formerly known as primary pulmonary hypertension [PPH]) Eisenmenger's syndrome Other pulmonary vascular diseases
Group C (cystic fibrosis or immunodeficiency disorders)	<ul style="list-style-type: none"> Cystic fibrosis (CF) Immunodeficiency disorders such as hypogammaglobulinemia
Group D (restrictive lung disease)	<ul style="list-style-type: none"> Idiopathic pulmonary fibrosis (IPF) Pulmonary fibrosis due to other causes Sarcoidosis with mean PA pressure > 30 mmHg Obliterative bronchiolitis (nonretransplant)

Source: Revision to policy 3.7.6.1.

ADDENDUM

GUIDANCE FOR LUNG TRANSPLANT FOR IRREVERSIBLE PULMONARY FAILURE FROM COVID-19

Background: Transplant has been successful for other conditions, including infections, that lead to irreversible pulmonary failure, so this disease has some familiar aspects within the lung transplant community. Because of the specific conditions surrounding the effects of SARS-CoV-2, and because much of the mechanism underlying the development of lung injury and recovery are still unclear, the following elements are recommended for any consideration for referral of and authorizations for potential candidates for lung transplant. The below represent elements, *IN ADDITION TO THE USUAL CRITERIA PROVIDED IN THE CMS LUNG PATIENT REFERRAL GUIDELINES*:

- Age under 65 if ECMO has been used as bridge to transplant
- Disease has progressed in spite of maximal non-invasive ventilatory support
- No other significant organ dysfunction exists
- Sufficient time for recovery must be allowed: once on invasive mechanical support or ECMO, referral should not be considered fewer than 4-6 weeks after ventilator-dependent or ECMO-supported pulmonary failure
- Patients on prolonged O₂ therapy other than mechanical support or ECMO should be given sufficient time to determine irreversibility of the condition (usually three months) and should be ambulatory with good opportunity for rehabilitation.
- Evidence of irreversible lung disease (bullae, fibrosis) must be present
- The ability to gain patient, not surrogate, approval for transplant is an essential ethical concept in light of the relatively poor long-term outcomes from lung transplant
- Ability to do adequate pulmonary rehabilitation while on support for respiratory failure
- Have 2 negative SARS-COV-2 PCR tests at least 24 hours apart with one of the samples being a deep respiratory specimen.
- Transplants should be performed only at lung transplant programs experienced in the highest risk lung transplants including familiarity with transplanting patients with ECMO bridging to transplant. Furthermore, they should have:
 - Broad donor pool (represented by low time to transplant measures), and
 - Low wait-list mortality

Reference: Cypel M, Keshavjee S. Comment When to consider lung transplantation for COVID-19. *Lancet Respir Med.* 2020;8:944–6. [https://doi.org/10.1016/S2213-2600\(20\)30393-3](https://doi.org/10.1016/S2213-2600(20)30393-3).

Footnotes

1. See Addendum 1, New system for lung allocation (enclosed)
2. Orens, JB, et al, 'International Guidelines for the Selection of Lung Transplant Candidates: 2006 Update - A Consensus Report from the Pulmonary Scientific Council of the International Society for Heart and Lung Transplantation', *Journal of Heart and Lung Transplantation*, 25(7), July 2006, 745-755.
3. Weill D, et al. A consensus document for the selection of lung transplant candidates: 2014 An update from the Pulmonary Transplantation Council of the International Society for Heart and Lung Transplantation. *J Heart Lung Transplant* 2015; 34:1–15
4. *Liver Transplantation* 2006, .12:813-820. Alcohol consumption patterns and predictors of use following liver transplantation for alcoholic liver disease.
5. *Liver Transplant Surg.*, 1997, Vol 3, 304 – 310. The natural history of alcoholism and its relationship to liver transplantation.
6. 6. Alcohol abstinence prior to liver transplantation for Alcoholic Liver Disease (G110807), *TPMG New Medical Technology*
7. *J Thorac Dis.* 2019 Sep; 11(Suppl 14): S1708–S1720.
8. 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.
9. 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).
10. *Journal of Heart and Lung Transplantation Vol. 18 (8), August 1999, pg 750-761*
11. *The Journal of Heart and Lung Transplantation* 2010; 29 (9), 1026 – 1033. Impact of Recipient Body Mass Index on Survival after Lung Transplantation.
12. Potential candidate for Heart/Lung transplantation will be evaluated independently.
13. *Annals of Surgery*, 2006. Vol.244 (4) 491-497.
14. Lung Transplantation in Advanced COPD: Is it Worth it? *Semin Respir Crit Care Med.* 2010 June; 31(3): 365-372; Selecting lung transplant candidates: where do current guidelines fall short? *Expert Rev Respir Med.* 2012 February; 6(1): 51-61.
15. *Amer Rev Respir Dis* 140: S92 and S95 1989; *Ann Int Med* 99: 612: 1983; *New England Journal of Medicine*, 1999 340(14), 1081-91
16. Celli BR, Cote CG, Marin JM et al. The body-mass index, airflow obstruction, dyspnea, and exercise capacity index in chronic obstructive pulmonary disease. *N Engl J Med* 2004;350:1005-12.
17. Applicable to idiopathic pulmonary arterial hypertension, familial pulmonary arterial hypertension, collagen vascular disease limited to the lungs, pulmonary veno-occlusive disease, pulmonary capillary hemangiomatosis, and drug induced pulmonary hypertension. *CHEST*, 2004, Volume 126 (Supplement 1).
18. *AJRCCM* 201. 184: 159-171 - Thorough review of lung transplantation; *J Heart Lung Transplant.* 2006. 25(7): 745-55. - Consensus report from ISHLT *Pulm Circ.* 2011. April-June. 1(2): 182-191 - PH and lung transplant.
19. *Transplantation.* 2010 Aug 15. 90(3): 298-305. - Suggests that 6MWD \leq 300 m and RAP \geq 14 mm Hg is better predictor of wait list mortality than LAS scoring system.
20. McGoon MD and Miller DP. *Eur Respir Rev.* 2012; 21(123):8-18.
21. *Ann Int Med* 115: 343 1991
22. Weill D, et al. A consensus document for the selection of lung transplant candidates: 2014 An update from the Pulmonary Transplantation Council of the International Society for Heart and Lung Transplantation. *J Heart Lung Transplant* 2015; 34:1–15
23. Nathan, SD., Lung Transplantation- Disease-Specific Considerations for Referral', *CHEST* 2005; 127: 1006-1016.
24. OPTN Policy 10: Allocation of Lungs, 10.1.F.i Lung Disease Diagnosis Groups, Effective Date 9/1/2016

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Lung transplant is a last resort treatment for end stage lung disease. The first human transplant was conducted in 1965. The first successful single lung transplant was done in 1983.

The diseases treated by lung transplants include:

- chronic obstructive pulmonary disease (COPD), including emphysema;
- idiopathic pulmonary fibrosis;
- cystic fibrosis;
- idiopathic (formerly known as "primary") pulmonary hypertension;

- alpha 1-antitrypsin deficiency;
- replacing previously transplanted lungs that have since failed;
- other causes, including bronchiectasis and sarcoidosis.

Prior to 2005, donor lungs were allocated by the United Network for Organ Sharing on a first-come, first-serve basis to patients on the transplant list. This was replaced by the current system, in which prospective lung recipients of age of 12 and older are assigned a lung allocation score or LAS, which takes into account various measures of the patient's health. The new system allocates donated lungs according to the immediacy of need rather than how long a patient has been on the transplant list. Patients who are under the age of 12 are still given priority based on how long they have been on the transplant waitlist. The length of time spent on the list is also the deciding factor when multiple patients have the same lung allocation score.

Patients who are accepted as good potential transplant candidates must carry a pager with them at all times in case a donor organ becomes available. These patients must also be prepared to move to their chosen transplant center at a moment's notice and relocate to within close proximity of the center. Such patients may be encouraged to limit their travel within a certain geographical region in order to facilitate rapid transport to a transplant center.

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.

Transplant, Lung, Single-7/12/91 Single lung transplantation is efficacious for appropriately selected patients.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC 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

Medicare – Considered not medically necessary

Non-Medicare – Considered medically necessary when criteria in the applicable policy statements listed above are met

CPT® or HCPC Codes	Description
0494T	Surgical preparation and cannulation of marginal (extended) cadaver donor lung(s) to ex vivo organ perfusion system, including decannulation, separation from the perfusion system, and cold preservation of the allograft prior to implantation, when performed
0495T	Initiation and monitoring marginal (extended) cadaver donor lung(s) organ perfusion system by physician or qualified health care professional, including physiological and laboratory assessment (eg, pulmonary artery flow, pulmonary artery pressure, left atrial pressure, pulmonary vascular resistance, mean/peak and plateau airway pressure, dynamic compliance and perfusate gas analysis), including bronchoscopy and X ray when performed; first two hours in sterile field
0496T	Initiation and monitoring marginal (extended) cadaver donor lung(s) organ perfusion system by physician or qualified health care professional, including physiological and laboratory assessment (eg, pulmonary artery flow, pulmonary artery pressure, left atrial pressure, pulmonary vascular resistance, mean/peak and plateau airway pressure, dynamic compliance and perfusate gas analysis), including bronchoscopy and X ray when performed; each additional hour (List separately in addition to code for primary procedure)

S2060	Lobar lung transplantation *S codes not covered by Medicare
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***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

**To verify authorization requirements for a specific code by plan type, please use the [Pre-authorization Code Check](#).

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Date Created	Date Reviewed	Date Last Revised
05/1996	04/06/2010 ^{MDCRPC} , 02/10/2011 ^{MDCRPC} , 12/06/2011 ^{MDCRPC} , 05/01/2012 ^{MDCRPC} , 03/05/2013 ^{MDCRPC} , 01/07/2014 ^{MDCRPC} , 11/04/2014 ^{MPC} , 09/01/2015 ^{MPC} , 07/05/2016 ^{MPC} , 05/02/2017 ^{MPC} , 03/06/2018 ^{MPC} , 03/05/2019 ^{MPC} , 03/03/2020 ^{MPC} , 03/02/2021 ^{MPC} , 03/01/2022 ^{MPC} , 03/07/2023 ^{MPC}	01/10/2022

^{MDCRPC} Medical Director Clinical Review and Policy Committee

^{MPC} Medical Policy Committee

Revision History	Description
03/05/2019	MPC approved to adopt KP National Criteria for Lung Transplant
09/03/2019	MPC approved to change General Principles 1.3 to <i>Uncontrollable infection is a contraindication to transplant</i> as recommended by KP National Transplant Services.
03/03/2020	MPC approved proposed changes from KP National Transplant Services
04/06/2021	MPC approved proposed changes from KP National Transplant Services. Requires 60-day notice, effective date September 1, 2021.
01/10/2022	MPC approved proposed changes from KP National Transplant Services. 60-day notice is not required.