LUNG, HEART/LUNG TRANSPLANTATION PATIENT SELECTION CRITERIA

The following are current, generally accepted, criteria for lung, heart/lung transplantation. These criteria are used as guidelines for referral for transplant evaluation and 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. BASIC PRINCIPLES
1.1. End stage lung disease that has failed maximal medical therapy.
1.2. Patients must have adequate social support systems and display a proven record of adherence to medical treatment. Additionally, patients must be willing to travel within short notice to the HealthSpan approved transplant Center of Excellence and, if necessary, return for treatment of complications.
1.3. No life-threatening or limiting disease in another organ system.
1.4. Ambulatory with rehabilitation potential.
1.5. Patients are required to be tobacco free and nicotine free for 6 months. Monitoring is required.

2. INDICATIONS
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.

3. CONTRAINDICATIONS
3.1. Invasive mechanical ventilator support.
3.2. Unresolved infection (except in cystic fibrosis and bronchiectasis).

i See Addendum 1, new system for lung allocation (enclosed)
iii Potential candidate for heart/lung transplant will be evaluated independently.
iv 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,

3.3. Other systemic diseases including but not limited to:

3.3.1. 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.

3.3.2. Diabetes with end organ effects; i.e., renal, cardiac or uncorrectable peripheral vascular disease. Insulin use itself is not a contraindication.

3.3.3. Uncontrolled hypertension.

3.3.4. Significant neurologic disease impairing cognitive function.

3.3.5. Malnutrition.

3.3.6. Obesity >140% ideal body weight or BMI >32 kg/m² (with an understanding that a BMI ≤30 will be necessary for transplantation).

3.3.7. Advanced hepatic dysfunction.

3.3.8. 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.

3.3.9. Evidence of clinically significant obstructive coronary artery disease and/or LVEF <40%.

3.3.10. Active or unresolved peptic ulcer disease.

3.4. Psycho-social behavioral and support issues, such as:

3.4.1. Active alcohol and/or substance abuse: Patients must be free for six (6) months from alcohol and other substance abuse 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.

3.4.2. Active nicotine abuse. Patients must be free from tobacco use for the previous six (6) months.

3.4.3. Lack of an adequate support system provided by family, friends, or others to support the patient before, during, and after the transplant process.

3.4.4. Active psychological and/or psychiatric conditions that have been evaluated by a mental health professional and found to render the patient unsuitable for transplantation.

3.4.5. Demonstrated lack of compliance with a complex medical regimen, as evidenced by failure to keep appointment, failure to make steady progress in completing pre-transplant evaluation testing, non-adherence to medication regimens or failure to adhere to testing required for maintenance on the waiting list.

v 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 Cyclopedia Medical Dictionary).

vi Body Mass Index (BMI) = (weight [kg] / height² [m²]). Percent Ideal Body Weight (PIBW) was calculated as follows: Men IBW = 106 pounds for the first 5 feet of height, add 6 pounds for each additional inch. Women IBW = 100 pounds for the first 5 feet of height, add 5 pounds for each additional inch. Journal of Heart and Lung Transplantation Vol. 18 (8), August 1999, pg 750-761


viii Potential candidate for Heart/Lung transplantation will be evaluated independently.

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

4. RELATIVE CONTRAINDICATIONS
4.1. Patients with previous thoracotomy and/or sclerosing procedures should be considered on case by case basis.
4.2. Systemic corticosteroid therapy >10 mgs prednisone daily.
4.3. Esophageal dysmotility and free reflux. Surgical repair may be necessary.xii
4.4. Very selective patients, whose hepatitis B is under full control, may be considered as candidates.
4.5. Hepatitis C is not a contraindication if transaminase is normal and, if necessary, the liver biopsy shows minimal pathology.
4.6. Age >65 for single lung, age >65 for sequential single lung and age > 55 for heart/lung.
4.7. History of disabling psychiatric illness.
4.8. Symptomatic osteoporosis.
4.9. Major mechanical chest deformity (such as kyphoscoliosis).
4.10. Active infection, or high risk of reactivation of previous infection, including, but not limited to, Hepatitis B.
xi Alcohol abstinence prior to liver transplantation for Alcoholic Liver Disease (G110807), *TPMG New Medical Technology*

PATIENT PROFILE FOR COMMON DIAGNOSES
LUNG TRANSPLANT REFERRAL GUIDELINES

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

1. GROUP A – Obstructive Lung Disease (See Table 1 Below)
1.1. FEV₁ < 25 %
1.2. DLCO < 40%
1.3. Hypoxemia; PO₂ < 55
1.4. Hypercapnia; PCO₂ > 51
*Amer Rev Respir Dis* 140: S92 and S95 1989

2. GROUP B – Pulmonary Arterial Hypertension (See Table 1 Below)xiii
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:
2.2.1. PA mean pressure > 55
2.2.2. World Health Organization (WHO) (New York Heart Association) class 3 or 4
2.2.3. 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.
2.3. Definite indications, after maximum pharmacologic treatment for referral includexiv:
2.3.1. Mean RA > 15 torr
2.3.2. Cardiac Index < 2L/minute/meter². Untreated, the mean survival for patients with these criteria are 10-11 months. -
2.3.3.
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).

AJRCCM, 158:335-339, 1998;
NEJM 338: 273-277, 1998;
Lancet Vol 358, pg. 1119-1123, 10/6/01;
NEJM Vol.346, #12, page 896 - 903, March 21, 2002

3. GROUP C – Cystic Fibrosis (See table 1 below)
3.1. FEV₁ < 40%
3.2. PO₂ < 55
3.3. Clinical deterioration as characterized by increasing number of hospitalizations, including recurrent pneumothorax, 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 pan-resistant organisms (Example: Burkholderia cepacia) have a relative contraindication.
3.6. Patients who are active on the UNOS waiting list for a cadaveric organ and are unlikely to survive the estimated wait time can be considered for living lobar transplant. Patients who have been approved for lung transplant evaluation by KP and are unlikely to survive the estimated wait time for a cadaveric transplant, can be considered for living lobar transplant.

4. GROUP D – Restrictive Lung Disease (See Table 1 Below)
4.1. Force Vital Capacity < 60%
4.2. Decline in Forced Vital Capacity of ≥10% during 6 months of follow-up.
4.3. Diffusing Capacity (corrected for alveolar volume) < 60%
4.4. Evidence of honey-combing in high resolution chest CT.
Lung transplant should be considered when a definite diagnosis of idiopathic pulmonary fibrosis is made.

5. OTHER CONDITIONS
Other conditions for which transplant may be appropriate includes the Lung diseases described in Table 1 below.

xv NEJM326: 1187 1992
AJRCCM, 158:335-339, 1998
JAMA, 286:2683-2689, 2001
AJ Epidemiology, 153:345-352, 2001
xvi Thorax 44: 280 1989
AJRCCM, 158:335 – 339, 1998
CHEST, 127 (3), 1005 – 1006, 2005
Table 1: Lung allocation score (LAS) primary diagnostic groupings for lung transplant candidates

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

Source: Revision to policy 3.7.6.1.