

MEDICAL POLICY



SUBJECT: HEART & HEART/LUNG TRANSPLANT	EFFECTIVE DATE: 07/02/99 REVISED DATE: 05/17/01, 04/17/02, 07/17/03, 06/17/04, 03/17/05, 02/16/06, 02/15/07, 01/17/08, 03/19/09, 03/18/10, 03/17/11, 03/15/12, 02/21/13, 02/20/14 ARCHIVED DATE: 02/19/15 EDITED DATE: 03/17/16, 03/16/17, 03/15/18 PAGE: 1 OF: 6
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<ul style="list-style-type: none">• <i>If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.</i>• <i>If a commercial product, including an Essential Plan product, covers a specific service, medical policy criteria apply to the benefit.</i>• <i>If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.</i>	

POLICY STATEMENT:

I. Heart Transplant:

- A. Improved outcomes in the treatment of heart failure in response to medical therapy, coupled with the critical shortage of donor organs, makes it imperative to restrict heart transplants to patients who are most disabled and are likely to derive the maximum benefit from transplantation. Hemodynamic and functional criteria are helpful in identifying these patients.

Based upon our criteria and review of the peer-reviewed literature heart transplantation for carefully selected individuals with end-stage heart disease that is unresponsive to any other medical or surgical therapeutic measures has been medically proven to be effective and therefore **medically appropriate** when recipient selection criteria has been met.

- B. The following are guidelines set forth by the American College of Cardiology (ACC) and the United Network for Organ Sharing (UNOS) and will be utilized in considering recipients for heart transplantation. The following are acceptable, probable and inadequate listing criteria guidelines for potential transplant patients:

1. *Acceptable* indications for cardiac transplantation, any of the following:
 - a. Maximal VO_{2max} (peak exercise oxygen consumption) less than 10ml/kg/min with achievement of anaerobic metabolism;
 - b. Severe ischemia consistently limiting routine activity not amenable to bypass surgery or angioplasty;
 - c. Recurrent symptomatic ventricular arrhythmias refractory to ALL therapeutic modalities; and
 - d. Cardiogenic shock or low output state requiring mechanical or inotropic support.
2. *Probable* indications for cardiac transplantation:
 - a. Symptomatic heart failure with peak VO_{2max} less than 14 ml/kg/min;
 - b. Recurrent unstable ischemia not amenable to bypass surgery or angioplasty; and
 - c. Instability of fluid balance/renal function not due to patient non-compliance with regime of weight monitoring, flexible use of diuretic drugs, and salt restriction.
3. *Inadequate* indications for cardiac transplantation:
 - a. Ejection fraction less than 20% with mild to moderate symptoms;
 - b. History of functional class (NYHA Class) III or IV symptoms or transient need for inotropic support on a suboptimal medical regime;
 - c. Previous ventricular arrhythmias that are now controlled; and
 - d. Maximal VO_{2max} greater than 15 ml/kg/min without other indications.

- C. UNOS has developed a method for prioritizing patients awaiting donor hearts assuring equitable distribution of organs. The system establishes objective medical urgency status levels that ensure that patients who have the most urgent medical need and have a high likelihood of survival following surgery have the best chance of getting an organ. The levels are Status 1A, 1B, 2 and Status 7 based on the severity of illness, the need for

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mechanical assist devices and life expectancy. There are separate status criteria for pediatric patients. The UNOS Adult Thoracic Organ Status criteria are:

Status 1A patients are admitted to the listing transplant center hospital and have at least one of the following devices or therapies in place:

1. Mechanical circulatory support for acute hemodynamic decompensation that include at least one of the following:
 - a. Intra-aortic balloon pump,
 - b. Implanted ventricular assist device,
 - c. Total artificial heart, or
 - d. Extracorporeal membrane oxygenator (ECMO).
2. Mechanical circulatory support with objective evidence of significant device-related complications such as thromboembolism, device infection, mechanical failure and /or life-threatening ventricular arrhythmias.
3. Continuous mechanical ventilation.
4. Continuous infusion of inotropic drug therapy.

Status 1B patients have at least one of the following devices or therapies in place:

1. Continuous intravenous inotropic drug therapy; or
2. Implanted ventricular assist device.

Status 2 patients do not meet the higher urgency criteria for Status 1A or 1B.

Status 7 patients are considered temporarily unsuitable to receive a thoracic organ transplant.

II. Heart-Lung Transplant:

Based upon our criteria and review of the peer-reviewed literature, *heart-lung transplantation* for carefully selected individuals with end-stage cardiac and pulmonary disease that is unresponsive to any other medical or surgical therapeutic measures has been medically proven to be effective and therefore **medically appropriate** when recipient selection criteria has been met.

The diagnoses appropriate for consideration for heart-lung transplantation include but are not limited to:

1. Irreversible primary pulmonary hypertension with heart failure;
2. Non-specific severe pulmonary fibrosis;
3. Eisenmenger complex with irreversible pulmonary hypertension and heart failure;
4. Cystic fibrosis with severe heart failure;
5. Chronic obstructive pulmonary disease with heart failure;
6. Emphysema with severe heart failure; and
7. Pulmonary fibrosis with uncontrollable pulmonary hypertension or heart failure.

III. Recipient Selection Guidelines:

Each individual considered for thoracic transplantation will be evaluated by the transplant center for potential difficulties that would complicate and diminish the success of transplantation. Consideration will be given to the patient's risk of death without transplantation, along with the presence and severity of potential contraindications to transplantation.

IV. Relative contraindications to heart or heart lung transplantation include, but are not limited to:

- A. For heart transplantation alone:
 1. Pulmonary hypertension; and
 2. Severe pulmonary disease (an FEV₁ of less than 50% predicted) despite optimal medical therapy;
- B. Irreversible hepatic dysfunction;
- C. Irreversible renal dysfunction;

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- D. Systemic infection making immune suppression unsafe including but not limited to hepatitis b virus, cytomegalovirus (positive donor to a negative recipient), HIV infection unless ALL of the following criteria are met:
 1. CD4 count greater than 200 cells/mm³,
 2. HIV-1RNA undetectable,
 3. On stable anti-retroviral therapy greater than 3 months,
 4. No other complications from AIDS (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidioidomycosis; resistant fungal infections, Kaposi's sarcoma, or other neoplasm), and
 5. Meets all other criteria for transplantation;
- E. Psychosocial instability - a pattern of non-adherence to medical therapies to such a degree it may jeopardize the success of a transplant;
- F. Neuromuscular neurological disorder that necessitates chronic placement with no likelihood of improvement.
- G. Presence of malignancy (other than non-melanoma skin cancers) or unless malignancy has been completely resected or unless (upon medical review) it is determined that malignancy has been treated with small likelihood of recurrence and acceptable future risks;
- H. Other life-limiting illness or conditions;
- I. History of ongoing or recent substance abuse; including nicotine addiction;
- J. Active peptic ulcer disease; and
- K. Severe peripheral vascular disease.

POLICY GUIDELINES:

- I. Prior authorization is contract dependent. Approvals for all transplants, including arrangements with an approved transplant center, may be required.
- II. Pre-transplant evaluation documentation could include the following clinical information. If testing is unable to be performed, the rationale for not performing the testing should be included in the documentation:
 - A. Clinical Evaluation:
 1. Confirmation of diagnosis;
 2. Identification of comorbidities;
 3. Treatment of co-morbidities;
 4. Current assessment of co-morbidities;
 5. Consult notes (if applicable).
 - B. Psycho-Social Evaluation:
 1. Karnofsky performance score;
 2. Identification of stressors (family support, noncompliance issues, motivational issues, alcohol or substance abuse).
 - C. Dental Evaluation.
 - D. Lab Tests:
 1. CBC, metabolic profile;
 2. Serologies: CMV,
 3. Hepatitis B and C;
 4. HIV Testing.
 - E. Cardiac Assessment:
 1. 12Lead EKG;
 2. Stress echo or MUGA Scan.

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- F. Pulmonary Assessment:
 1. Chest x-ray;
 2. Pulmonary function tests (PFTs).
 3. Low dose screening CT for individuals considered high-risk for lung cancer (e.g., 20-30 pack history of smoking).
- G. Age Appropriate Screening Tests:
 - A. Age greater than or equal to 50 years:
 - a. Colonoscopy (within 10 years); or
 - b. Flexible sigmoidoscopy (within 5 years); or
 - c. Guaiac stool testing (within 1 year); or
 - d. Rationale of contraindication to testing (if applicable).
 2. Women age 21-70 years:
 - a. Pap smear (within 3 years).
 3. Women age greater than or equal to 40 years:
 - a. Mammogram (within 2 years).

DESCRIPTION:

A heart transplant involves replacing a diseased heart with a healthy donor heart. The combined heart-lung transplantation is intended to prolong survival and improve function in patients with end-stage cardiopulmonary or pulmonary disease that have been unresponsive to any other therapies. These procedures are performed on *selected* patients with end stage heart and pulmonary disease.

RATIONALE:

Heart and heart/lung transplantation represents the only curative approach for many carefully screened patients with end-stage or congenital heart and pulmonary disease. Transplantation is limited due to the profound shortage of donor hearts and lungs.

Advances in donor and recipient selection, improved surgical techniques, new immunosuppressive drugs, and better management of infections have improved long term survival.

Solid organ transplantation for candidates that are HIV positive has long been controversial, due to the long-term prognosis for HIV positivity, and the impact of immunosuppression on HIV disease. Although HIV+ transplant recipients may be a research interest of some transplant centers, the minimal data regarding long-term outcome in these patients consist primarily of case reports and abstract presentations of liver and kidney recipients. Nevertheless, some transplant surgeons would argue that HIV positivity is no longer an absolute contraindication to transplant due to the advent of highly active antiretroviral therapy (HAART), which has markedly changed the natural history of the disease. Furthermore, UNOS states that asymptomatic HIV+ patients should not necessarily be excluded for candidacy for organ transplantation, stating “A potential candidate for organ transplantation whose test for HIV is positive but who is in an asymptomatic state should not necessarily be excluded from candidacy for organ transplantation, but should be advised that he or she may be at increased risk of morbidity and mortality because of immunosuppressive therapy.” In 2001, the Clinical Practice Committee of the American Society of Transplantation proposed that the presence of AIDS could be considered a contraindication to kidney transplant unless the specific criteria were present. These criteria are listed in this policy regarding HIV status and heart transplants.

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CODES: Number Description

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

CPT:	33933	Backbench standard preparation of cadaver donor heart/lung allograft prior to transplantation, including dissection of allograft from surrounding soft tissues to prepare aorta, superior vena cava, inferior vena cava, and trachea for implantation
	33935	Heart-lung transplant with recipient cardiectomy-pneumonectomy
	33944	Backbench standard preparation of cadaver donor heart/lung allograft prior to transplantation, including dissection of allograft from surrounding soft tissues to prepare aorta, superior vena cava, inferior vena cava, pulmonary artery, and left atrium for implantation
	33945	Heart transplant, with or without recipient cardiectomy

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HCPCS: No code

ICD10: Various

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*key article

KEY WORDS:

Heart transplant, Lung transplant

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) for Heart Transplants. Please refer to the following NCD website for Medicare Members: <http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=112&ncdver=3&bc=AgAAgAAAAAAA&>.