



**Subject:** *Heart-lung Transplant*

**Number:** *200308-0006*

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**Important note**

Even though this policy may indicate that a particular service or supply is considered covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. You need to consult the *Evidence of Coverage* to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and your plan of benefits, the provisions of your benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans. With respect to Medicare and Medicaid members, this policy will apply unless Medicare and Medicaid policies extend coverage beyond this Medical Policy and Criteria Statement. Medicare and Medicaid policies will only apply to benefits paid for under Medicare or Medicaid rules, and not to any other health benefit plan benefits. CMS's Coverage Issues Manual can be found on the following Web site: <http://www.cms.hhs.gov/manuals/pub06pdf/pub06pdf.asp>

**Overview**

A heart-lung transplant refers to the transplantation of one or both lungs and heart from a single donor. The donor still has a beating heart and functioning lungs, but is brain dead. The heart-lung transplant is intended to prolong survival and improve function in patients with end-stage cardiopulmonary or pulmonary diseases, such as congenital heart disease, primary pulmonary hypertension, and cystic fibrosis. This type of transplant will not work for some diseases as the disease may damage the transplanted heart and/or lung in the same way it damaged the original organs.

**Policy and criteria**

**NOTE:** These services require prior authorization by the plan medical director.

**When services are covered:**

We cover **heart-lung transplants**, including harvesting of the donor organs and implanting the donor organs into recipients, for ANY of the following conditions (not an all-inclusive list) when the patient selection criteria are met:

- Chronic obstructive pulmonary disease with heart failure
- Cystic fibrosis with severe heart failure
- Eisenmenger's complex with irreversible pulmonary hypertension and heart failure
- Emphysema with severe heart failure
- Irreversible primary pulmonary hypertension with heart failure
- Non-complex congenital heart disease associated with pulmonary hypertension that is not amenable to lung transplantation and repair by standard cardiac surgery
- Non-specific severe pulmonary fibrosis with severe heart failure
- Pulmonary fibrosis with uncontrollable pulmonary hypertension or heart failure
- Severe coronary artery disease or cardiomyopathy with irreversible pulmonary hypertension
- Heart-lung transplantation may be covered for other congenital cardiopulmonary anomalies if it is determined to be medically necessary upon individual case review

In the absence of protocol set by the designated transplant facility, we cover heart-lung transplants when **all** of the **patient selection criteria** listed below are met:

1. New York Heart Association (NYHA) classification of heart failure III or IV (see Note below), but without severe disability; **and**
2. Life expectancy (in the absence of cardiopulmonary disease) of greater than two years; **and**
3. No malignancy (except for non-melanomatous skin cancers) **or** malignancy has been completely resected **or** (upon individual case review) malignancy has been adequately treated with no substantial likelihood of recurrence; **and**
4. Adequate functional status. Active rehabilitation is important to the success of the transplant. Under established guidelines, patients who are mechanically ventilated or otherwise immobile are considered poor candidates for transplantation.
5. Adequate liver and renal function, defined as a bilirubin of < 2.5 mg/dl and a creatinine clearance of > 50 ml/min/kg; **and**
6. Absence of active infections that are not effectively treated; **and**
7. Absence of chronic high-dose ( $\geq 30$  mg/day) steroid therapy. Patients on high-dose steroids are considered inappropriate candidates due to problems with bronchial healing.
8. Absence of uncontrolled HIV infection, defined as:
  - a. CD4 count greater than 200 cells/mm<sup>3</sup> for greater than six months; and
  - b. HIV-1 RNA (viral load) undetectable; and
  - c. On stable antiviral therapy greater than three months; and
  - d. No other complications from AIDS, such as opportunistic infections (e.g., aspergillus, tuberculosis, coccidioidomycosis, resistant fungal infections) or neoplasms (e.g., Kaposi's sarcoma, non-Hodgkin's lymphoma); **and**
9. No uncontrolled and/or untreated psychiatric disorders that interfere with compliance to a strict treatment regimen; **and**
10. No active alcohol, drug or tobacco dependency that interferes with compliance to a strict treatment regimen. Persons with a history of alcohol or drug abuse must be abstinent for at least six months before being considered for a transplant.

**Note:** NYHA Class III and Class IV for heart failure are defined as follows:

**Class III:** Patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity (i.e., mild exertion) causes fatigue, palpitation, dyspnea, or anginal pain.

**Class IV:** Patients with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms of cardiac insufficiency or of the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increased.

***When services are not covered:***

We **do not cover** heart-lung transplants when any of the following **contraindications** exist:

- Advanced age (generally over age 65)
- Active extra-pulmonary infection
- HIV seropositivity
- Insulin-dependent diabetes mellitus with evidence of end-organ damage, such as retinopathy, neuropathy, nephropathy, and peripheral or cerebrovascular disease
- Irreversible hepatic dysfunction
- Irreversible non-pulmonary organ dysfunction (liver failure: transaminases twice normal, with associated coagulopathy), irreversible renal dysfunction (creatinine clearance < 50 ml/min/kg)
- Malignancy (other than noted above) unless "cured" (some studies have suggested a five-year window to establish "cure")
- Presence of gastrointestinal disease, such as bleeding peptic ulcer, diverticulitis, chronic hepatitis, active or recurrent pancreatitis)
- Presence of multi-system disease. Patients with potentially multi-system diseases such as systemic sclerosis (scleroderma) or other collagen vascular diseases such as systemic lupus erythematosus

must be carefully evaluated to ensure that their disease is primarily confined to the lung. Patients with diabetes must be carefully evaluated to rule out significant diabetic complications (as previously noted).

- Previous thoracotomy involving pleurectomy or pleurodesis, as this poses increased risk of bleeding from chest wall adhesions
- Progressive neuromuscular disease
- Severe musculoskeletal disease with debilitating thoracic involvement
- Severe obesity, as evidenced by a Body Mass Index (BMI) of  $\geq 35$
- Smoking. Patients with a history of smoking must be abstinent for at least six months before being considered a candidate for the lung component of the transplant.
- Systemic hypertension that requires multiple pharmacotherapies
- Untreated or unstable cerebrovascular disease
- When other effective medical treatments or surgical options are available

**Note:** Heart-lung transplant is considered experimental and investigational for persons with the above contraindications.

The following are *relative* contraindications to heart-lung transplant. They may make the transplant more challenging, or in some cases, less likely to succeed long-term. Any one of these alone may not be a reason to decline the transplant request. However, two or more may make transplantation not the best option:

- Symptomatic or severe asymptomatic peripheral or cerebrovascular disease
- Previous thoracic surgery not involving pleurectomy or pleurodesis

Please refer to the *Transplant policy* for additional information regarding covered and noncovered services.

We **do not cover heart xenotransplantation** (e.g., porcine xenografts) for ANY cardiac conditions because it is considered investigational and experimental.

We **do not cover total artificial heart** (e.g., ABIOCOR Total Artificial Heart, CardioWest Total Artificial Heart) as an alternative to heart transplantation as it is considered investigational and experimental.

We **do not cover heart transplants that require concurrent coronary artery bypass graft surgery**, as this is experimental. However, we do cover donor hearts that are considered “high risk” because of advanced age.

#### **FCHP products to which this policy applies:**

- ⊕ FCHP Direct and FCHP Select Care (HMO)
- ⊕ FCHP Flex Care Direct and Select (POS)
- ⊕ Fallon Preferred Care (PPO)
- ⊕ FCHP MassHealth
- ⊕ Major Medical
- ⊕ Non-Group: FCHP Independent Care, Direct enrollment and Bill-at-home
- ⊘ Medicare plan – *reminder* to refer to CMS for policy and criteria

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**Committee review dates:**

**Technology Assessment Committee:** 11/2003

Approved by:	<i>Signature on file</i>	8/27/2003
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