



**Subject:** *Heart Transplant*

**Number:** *200308-0005*

Effective date: 08/25/2003

Revision date(s): 08/11/2003

**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 transplant consists of replacing an end-stage diseased heart with a healthy donor heart. Donors still have a beating heart and functioning lungs, but are brain-dead.

In adults, the most common indications for heart transplantations are cardiomyopathy (about 50%), coronary artery disease (about 40%), valvular disease (about 4%), retransplantation following a failed primary transplantation (about 2%) and congenital heart disease (about 2%). In children, the most common indications for heart transplantation are congenital heart disease (about 47%), dilated cardiomyopathy (about 45%), and retransplantation (about 3%).

**Policy and criteria**

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

**When services are covered:**

We cover **heart transplants** for **any** of the following conditions (not an all-inclusive list):

- Irreversible, terminal heart disease with <50% one-year life expectancy
- Symptoms are refractory or intolerable (NYHA Class III or IV), despite maximal medical therapy with digitalis, diuretics, and vasodilators at maximally-tolerated doses
- Left ventricular ejection fraction (LVEF) < 35% despite maximal medical therapy
- End-stage ventricular failure
- Idiopathic dilated cardiomyopathy
- Nutritional and metabolic cardiomyopathy
- Postpartum cardiomyopathy
- Intractable coronary artery disease
- Valvular heart disease
- Heart disease that is not amenable to revascularization or valvular surgery for critical aortic valve disease, or for severe mitral regurgitation
- Cardiac arrhythmia
- Peak oxygen consumption of 14 ml/kg/min or less

- Cardiac retransplantation due to graft failure
- Congenital heart disease
- Inability to be weaned from temporary cardiac-assist devices after myocardial infarction or non-transplant cardiac surgery
- Myocarditis

In the absence of protocol set by the designated transplant facility, we cover heart 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 - *does not apply to pediatric patients*; **and**
2. Life expectancy (in the absence of cardiovascular disease) of greater than 2 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 pulmonary, liver and renal function; **and**
5. Absence of active infections that are not effectively treated; **and**
6. 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**
7. Absence of active or recurrent pancreatitis; **and**
8. Absence of diabetes with end-organ damage (neuropathy, nephropathy, retinopathy); **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.

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

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

We **do not cover** heart transplant when any of the following **contraindications** exist:

- Advanced age (generally over age 65)
- Cross-match incompatibility between recipient and donor
- Myocardial infiltrative or inflammatory disease
- Alcoholic cardiomyopathy
- Need for second organ transplant (kidney, liver, or hematopoietic progenitor cell) other than lung
- A systemic illness or disease that would limit life expectancy or compromise recovery from cardiac transplantation (e.g., autoimmune, collagen vascular disease, amyloidosis)
- Insulin-dependent diabetes mellitus with evidence of end-organ complications, such as retinopathy, neuropathy, nephropathy, and peripheral or cerebrovascular disease

- Systemic hypertension requiring multi-drug therapy for even moderate control (due to difficult cyclosporin management)
- Acute severe hemodynamic compromise at time of transplant, when accompanied by failure of any vital end-organ, because survival is likely to be compromised
- Severe peripheral vascular disease or cerebrovascular disease
- Malignancy, life-threatening, current or past (some studies have suggested a five-year window to establish “cure”)
- Active infection
- Presence of HIV/AIDS with profound immunosuppression (CD4 count < 200 cells/mm<sup>3</sup>)
- Irreversible hepatic dysfunction (transaminases twice normal, with associated coagulopathy)
- Presence of hepatitis B antigen
- Irreversible renal dysfunction (serum creatinine > 2 mg/dl or clearance < 50 cc/min)
- Pulmonary hypertension (over 5 Wood’s units, or PA systolic > 65 mm Hg) unless pulmonary vasodilators can reduce pulmonary vascular resistance (PVR) to less than 3 Wood’s units **and** PA systolic < 50
- Peak oxygen consumption greater than 14 ml/kg/min, based on likely prognosis, since these patients are not considered appropriate for transplant (as per the American College of Cardiology)
- Peak oxygen consumption greater than 20 ml/kg/min (or > 75% predicted), since these patients are considered "too well" for transplant (as per the American College of Cardiology)
- Chronic bronchitis or chronic obstructive pulmonary disease, as evidenced by forced expiratory volume in 1 second (FEV<sub>1</sub>) <60% predicted, or any irreversible lung disease
- Pulmonary infarction or embolism during the preceding eight weeks
- Presence of life threatening neuromuscular disorders
- Presence of bleeding peptic ulcer, which may be exacerbated by transplant
- Presence of diverticulitis, which may be exacerbated by immunosuppression
- Severe obesity, as evidenced by a Body Mass Index (BMI) of ≥ 35
- Severe osteoporosis
- Alcohol, drug or tobacco use. Persons with a history of alcohol or drug abuse must be abstinent for at least six months before being considered for a transplant.
- Psychosocial instability

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

**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

## References

1. Adams DH, Chen RH, Kadner A. Cardiac xenotransplantation: Clinical experience and future direction. *Ann Thorac Surg.* 2000;70(1):320-326.
2. Addonizio LJ, Hsu DT, Douglas JF, et al. Decreasing incidence of coronary disease in pediatric cardiac transplant recipients using increased immunosuppression. *Circulation.* 1993;88(5 Pt 2):II224-II229.
3. AHA Medical/Scientific Statement. Selection and treatment of candidate for heart transplantation. *Circulation* 1995;92:3593-3612
4. Allen MD, Fishbein DP, McBride M, et al. Who gets a heart? Rationing and rationalizing in heart transplantation. *West J Med.* 1997;166(5):326-336.
5. Alpert JS. Left ventricular assist devices reduced the risk for death and increased 1-year survival in chronic end-stage heart failure. *ACP J Club.* 2002;136(3):88.
6. American College of Cardiology (ACC) has established recipient guidelines for potential heart transplant recipients
7. Arabia F A, Copeland JG, Pavie A, Smith RG. Implantation technique for the CardioWest total artificial heart. *Ann Thorac Surg.* 1999;68:698-704.
8. Arabia FA. Update on the total artificial heart. *J Card Surg.* 2001;16(3):222-227.
9. Benson L, Freedom RM, Gersony W, et al. Session II: Cardiac replacement in infants and children: Indication and limitations. *J Heart Lung Transplant.* 1991;10(5 Pt 2):791-801.
10. Cooley DA. The total artificial heart. *Nat Med.* 2003;9(1):108-111.
11. Copeland JG, Arabia FA, Banchy ME, et al. The CardioWest total artificial heart bridge to transplantation: 1993 to 1996 national trial. *Ann Thorac Surg.* 1998;66(5):1662-1669.
12. Copeland JG, Pavie A, Duveau D, et al. Bridge to transplantation with the CardioWest total artificial heart: the international experience 1993 to 1995. *J Heart Lung Transplant.* 1996;15(1 Pt 1):94-99.
13. Deng MC, Smits JM, Packer M. Selecting patients for heart transplantation: Which patients are too well for transplant? *Curr Opin Cardiol.* 2002;17(2):137-144.
14. DeRose JJ Jr, Oz MC. Surgical alternatives to transplantation and assist devices in the treatment of heart failure. *Curr Cardiol Rep.* 2000;2(6):564-571.
15. Francis GS, et al. Pathophysiology and diagnosis of heart failure. In: Hurst's The Heart. V Fuster, et al., eds. Ch. 20. 10<sup>th</sup> Ed. New York, NY: McGraw Hill; 2001; 655-685.
16. Frigerio M, Gronda EG, Mangiavacchi M, et al. Restrictive criteria for heart transplantation candidacy maximize survival of patients with advanced heart failure. *J Heart Lung Transplant.* 1997;16(2):160-168.
17. Hunt SA. Comment--the REMATCH trial: Long-term use of a left ventricular assist device for end-stage heart failure. *J Card Fail.* 2002;8(2):59-60.
18. Jayakar DV. Surgical treatment of chronic heart failure. What to tell patients about heart-saving options. *Postgrad Med.* 2001;109(3):61-70.
19. Johnson MR, Naftel DC, Hobbs RE, et al. The incremental risk of female sex in heart transplantation: A multiinstitutional study of peripartum cardiomyopathy and pregnancy. *Cardiac Transplant Research Database Group. J Heart Lung Transplant.* 1997;16(8):801-812.
20. Jouveshomme S, Baffert S, Fay A-F. Artificial heart (systematic review, expert panel). Paris, France: Comite d'Evaluation et de Diffusion des Innovations Technologiques (CEDIT), 1998:46.
21. Magliato KE, Trento A. Heart transplantation -- surgical results. *Heart Fail Rev.* 2001;6(3):213-219.
22. Morrow WR. Cardiomyopathy and heart transplantation in children. *Curr Opin Cardiol.* 2000;15(4):216-223.
23. Mudge GH, Goldstein S, Addonizio LJ et al. Task Force 3: Recipient Guidelines/Prioritization. *J Am Coll Cardiol* 1993;22:21-31
24. Mudge GH, Goldstein S, Addonizio LJ, et al. 24th Bethesda Conference: Cardiac transplantation. Task Force 3: Recipient guidelines/prioritization. *J Am Coll Cardiol.* 1993;22(1):21-31.
25. Muirhead J. Heart transplantation in children: Indications, complications, and management considerations. *J Cardiovasc Nurs.* 1992;6(3):44-55.
26. National Institutes of Health, National Heart, Lung & Blood Institute. Expert Panel Review of the NHLBI Total Artificial Heart (TAH) Program. June 1998 - November 1999. Bethesda, MD: NHLBI, April 2000.
27. Nose Y. Implantable total artificial heart developed by Abiomed gets FDA approval for clinical trials. *Artif Organs.* 2001;25(6):429. *Journal of the American College of Cardiology* 1993 vol. 21, no. 4, March 15, 1993; 975-81, by Spencer Kubo, et al.
28. Nose Y. Totally implantable total artificial heart for clinical application. *Artif Organs.* 2002;26(3):214-215.
29. Odum J, Laks H, Burch C, et al. Transplantation for congenital heart disease. *Adv Card Surg.* 2000;12:59-76.
30. Olivari MT, Windle JR. Cardiac transplantation in patients with refractory ventricular arrhythmias. *J Heart Lung Transplant.* 2000;19(8 Suppl):S38-S42.
31. Pennington DG, Noedel N, McBride LR, et al. Heart transplantation in children: An international survey. *Ann Thorac Surg.* 1991;52(3):710-715.

32. Recommendations of the Consensus Conference on Candidate Selection for Heart Transplantation 1993, Miller et al. 1995 J Heart Lung Transplant 14:562-571.
33. Remme WJ, Swedberg K. Guidelines for the diagnosis and treatment of chronic heart failure. Eur Heart J. 2001;22(17):1527-1560.
34. Rickenbacher PR, Rizeq MN, Hunt SA, et al. Long-term outcome after heart transplantation for peripartum cardiomyopathy. Am Heart J. 1994;127(5):1318-1323.
35. Rose EA, Gelijns AC, Moskowitz AJ, et al. Long-term mechanical left ventricular assistance for end-stage heart failure. N Engl J Med. 2001;345(20):1435-1443.
36. Sarris GE, Smith JA, Bernstein D, et al. Pediatric cardiac transplantation. The Stanford experience. Circulation 1994;90(5 Pt 2):II51-II55.
37. Selection and Treatment of Candidates for Heart Transplantation, approved by the American Heart Association Science Advisory and Coordinating Committee on July 24, 1995, published in Circulation 1995;92:3593-3612.
38. Shaddy RE, Naftel DC, Kirklin JK, et al. Outcome of cardiac transplantation in children. Survival in a contemporary multi-institutional experience. Pediatric Heart Transplant Study. Circulation. 1996;94(9 Suppl):II69-II73.
39. Slaughter MS, Braunlin E, Bolman RM 3rd, et al. Pediatric heart transplantation: Results of 2- and 5-year follow-up. J Heart Lung Transplant. 1994;13(4):624-630.
40. Steinman TI, Becker BN, Frost AE, et al. Guidelines for the referral and management of patients eligible for solid organ transplantation. Transplantation. 2001;71(9):1189-1204.
41. Stevenson LW, Warner SL, Steimle AE, et al. The impending crisis awaiting cardiac transplantation. Modeling a solution based on selection. Circulation. 1994;89(1):450-457.
42. The Journal of the American College of Cardiology guidelines from the Bethesda Conference, 1993
43. United Network for Organ Sharing (UNOS) guidelines for donor heart organs according to severity of illness

**Committee review dates:**

**Technology Assessment Committee:** 11/2003

Approved by:	<i>Signature on file</i>	8/20/2003
	Dennis A. Batey, M.D.	Date
	Medical Director for Utilization & Care Management	