

Corporate Medical Policy

Cardiac (Heart) Transplantation

File Name: cardiac_heart_transplantation
Origination: 1/1986
Last CAP Review: 6/2010
Next CAP Review: 6/2012
Last Review: 6/2010

Description of Procedure or Service

Heart transplantation is the surgical excision of a heart and the main arteries from a human, brain-dead donor, with subsequent implantation into a recipient who has had his heart surgically removed in a similar manner. The new heart is surgically attached to the major blood vessels which include the pulmonary arteries, pulmonary veins, aorta, and the vena cava.

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

BCBSNC will cover human heart transplantation when it is considered medically necessary because the medical criteria and guidelines shown below are met

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

Coverage is not provided for organs sold rather than donated to the recipient.

When Cardiac (Heart) Transplantation is covered

A. Benefit eligibility is considered for **adult** patients with end-stage, irreversible, refractory, symptomatic heart disease requiring maximal continuous medical and/or mechanical support and who have:

1. a low functional status, and
2. a poor probability of survival, and
3. one of the following underlying conditions:
 - a. presence of an implanted ventricular assist device, or
 - b. refractory cardiogenic shock, or
 - c. dependency on intravenous inotropic support to maintain adequate organ perfusion, or

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- d. maximal VO₂ of 11-14 milliliters/kilogram/minute (or 55% of predicted) and major limitation of activities, or
- e. severe ischemia (or recurrent unstable ischemia) consistently limiting routine activity not amenable to bypass surgery or percutaneous coronary intervention, or
- f. recurrent symptomatic ventricular arrhythmias refractory to all therapeutic modalities, or
- g. ischemic cardiomyopathy not amenable to medical therapy or revascularization procedures.

B. Benefit eligibility is considered for **pediatric** heart transplantation in the following clinical situations:

1. Patients with heart failure with persistent symptoms at rest who require one or more of the following:

- a. continuous infusion of intravenous inotropic agents, or
- b. mechanical ventilatory support, or
- c. mechanical circulatory support.

2. Patients with pediatric heart disease with symptoms of heart failure who do not meet the above criteria but who have:

- a. severe limitation of exercise and activity (if measurable, such patients would have a peak maximum oxygen consumption <50% predicted for age and sex), or
- b. cardiomyopathies or previously repaired or palliated congenital heart disease and significant growth failure attributable to the heart disease, or
- c. near sudden death and/or life-threatening arrhythmias untreatable with medications or an implantable defibrillator, or
- d. restrictive cardiomyopathy with reactive pulmonary hypertension, or
- e. reactive pulmonary hypertension and potential risk of developing fixed, irreversible elevation of pulmonary vascular resistance that could preclude orthotopic heart transplantation in the future, or
- f. anatomical and physiological conditions likely to worsen the natural history of congenital heart disease in infants with a functional single ventricle, or
- g. anatomical and physiological conditions that may lead to consideration for heart transplantation without systemic ventricular dysfunction.

Retransplantation in patients with graft failure, due to either technical reasons or hyperacute rejection is considered medically necessary.

Retransplantation in patients with chronic rejection, moderate graft vasculopathy or recurrent disease is considered medically necessary when the patient meets general patient selection criteria as outlined above.

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When Cardiac (Heart) Transplantation is not covered

A. Benefits for Human Heart Transplant are not available when any of the following clinical conditions are present:

1. Alcoholic cardiomyopathy (unless abstinent for at least 6 months),
2. Systemic illness that would limit life expectancy or compromise recovery from cardiac transplantation,
3. Diabetes mellitus with evidence of significant end-organ complications, such as retinopathy, neuropathy, nephropathy, and peripheral or cerebrovascular disease,
4. Acute severe hemodynamic compromise at the time of transplant, when accompanied by failure of any vital end-organ, because survival is likely to be compromised,
5. Severe peripheral vascular disease or cerebrovascular disease,
6. Malignancy, life threatening, current or past (some have suggested a five year window to establish "cure"),
7. Active infection (except for infection of a ventricular assist device),
8. Irreversible hepatic (liver) dysfunction (transaminases twice normal, with associated coagulopathy), irreversible renal (kidney) dysfunction (serum creatinine greater than 2 mg/dl or clearance less than 50 cc/min),
9. Chronic bronchitis or chronic obstructive pulmonary disease FEV 1 less than 60% predicted or any irreversible lung disease,
10. Cachexia, even without major end-organ failure, as survival is significantly less favorable,
11. Morbid obesity indicated by a BMI > 40, or a BMI > 35 with comorbid conditions,
12. Absence of documentation of nonsmoking status,
13. Recent substance abuse that will likely impair compliance with post transplant protocols,
14. Psychosocial instability,
15. HIV positivity.

B. Pulmonary infarction or embolism during the preceding eight weeks is considered a relative contra-indication.

C. Heart transplants that require planned concurrent coronary artery bypass graft surgery. This is considered experimental.

Policy Guidelines

Only those patients accepted for transplantation by a transplantation center and actively listed for transplant should be considered for prior review. Guidelines should be followed for transplant network or consortiums, if available.

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Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: 33940, 33944, 33945, S2152

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

Some sources of information on patient selection criteria for heart transplantation are:

National Heart, Lung and Blood Institute (NHLBI) criteria published in January 1984

Medicare guidelines (Federal Register. 1987;52:10949)

"Recipient Selection for Cardiac Transplantation," by George A. Pantely. In: Cardiac Transplantation: A Manual for Health Care Professionals, J.S. Hosenpud, ed. New York: Springer-Verlag, 1991

"Selection of Patients for Cardiac Transplantation," by Andrea Hastillo and Michael L. Hess. In: Cardiac Transplantation, Mark E. Thompson, ed. Philadelphia: F.A. Davis Company, 1990

BCBSA Medical Policy Reference Manual - 7/10/98

Specialty Matched Consultant Advisory Panel 11/1999

Medical Policy Advisory Group 12/2/1999

Specialty Matched Consultant Advisory Group - 12/2001

BCBSA Medical Policy Reference Manual - 4:2002, 7.03.09

Specialty Matched Consultant Advisory Group - 11/2003

Specialty Matched Consultant Advisory Panel - 11/2005

Hunt SA, Abraham WT, Chin MH, Feldman AM, Francis GS, Ganiats TG, et al. ACC/AHA 2005 Guideline update for the diagnosis and management of chronic heart failure in the adult. A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Update the 2001 Guidelines for the Evaluation and Management of Heart Failure). Retrieved 7/16/07 from http://www.guideline.gov/summary/summary.aspx?doc_id=7664&nbr=004463&string=cardiac+AND+transplant

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.09, 4/25/06

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BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.09, 8/13/09

Specialty Matched Consultant Advisory Panel 6/2010

Policy Implementation/Update Information

- 1/86 Original Policy: Generally accepted medical practice on an individual consideration basis
- 8/88 Reviewed: Eligible for coverage on an individual consideration basis
- 11/90 Revised: Coverage language
- 9/93 Revised: Patient selection criteria citations added to coverage section
- 11/96 Reaffirmed: National Association reviewed 7/96
- 9/99 Reformatted, Medical Term Definitions added.
- 12/99 Reaffirmed, Medical Policy Advisory Group
- 10/00 System coding changes.
- 1/01 Revised. Statements regarding the peak oxygen consumption levels under "When it is covered" and "When it is not covered" were removed.
- 12/01 Specialty Matched Consultant Advisory Group review. Changes made to When Cardiac (Heart) Transplant is not covered.
- 11/03 Biannual policy review. Specialty Matched Consultant Advisory Group review. Removed need for documentation of less than 50% survival over the next year for eligibility criteria. Changes made to noncovered section to include information on morbid obesity, smoking and drug addiction status Format changes for consistency.
- 4/04 Added code S2152 to Billing/Coding section.
- 1/6/05 Added code 33944 to Billing/Coding section.
- 11/17/05 Biennial review. Specialty Matched Consultant Advisory Panel review 11/7/05. In the section "When Cardiac Transplantation is not covered," the statement "insulin-dependent" removed from item 5 and "severe" added to description of complications. Item 6 regarding hypertension was deleted. No changes to coverage criteria.
- 11/19/07 Criteria for When Cardiac Transplantation is covered was revised. Added criteria for retransplantation. In the When it is not covered section, deleted Item 1 (age limitation) and Item 2 (myocardial infiltrative or inflammatory disease). Item 12 was moved to item 16 and revised to state "Pulmonary infarction or embolism during the preceding eight weeks is considered a relative contra-indication. Item 19 moved to Item 17 and revised to state "Heart transplants that require planned concurrent coronary artery bypass graft surgery." Updated medical terms and references. Specialty Matched Consultant Advisory Panel review meeting 10/29/07. No change to policy statement. (adn)
- 12/7/09 Medical criteria reformatted into numbered lists. Information regarding pediatric heart transplantation added to the When it is Covered section. Specialty Matched Consultant Advisory Panel review meeting 10/30/09. (adn)
- 8/3/2010 Specialty Matched Consultant Advisory Panel review meeting. Medical Policy number removed. No changes to policy statement.(mco)

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Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.