



# CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all health benefit plans administered by CIGNA Companies including plans formerly administered by Great-West Healthcare, which is now a part of CIGNA.

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## Subject Heart Transplantation

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 Cardiomyoplasty and Ventricular  
 Reshaping in the Treatment of Heart  
 Failure  
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 Transplant Donor Charges  
 Ventricular Assist Devices (VADs)

### INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations. Proprietary information of CIGNA. Copyright ©2011 CIGNA

## Coverage Policy

**CIGNA covers heart transplantation in an adult as medically necessary for the treatment of ANY of the following:**

- malignant ventricular arrhythmias unresponsive to medical and/or surgical therapy
- refractory angina that is not amenable or correctable by alternative medical or surgical therapies and leaves the individual in a New York Heart Association functional class III or IV
- end-stage intractable heart failure arising as a consequence of heart disease with ALL of the following:
  - disease that is not amenable or correctable by alternative medical or surgical therapies
  - disease that, optimally managed, leaves the individual in New York Heart Association class III or IV
  - life expectancy <50% at one year without heart transplantation

**CIGNA covers heart transplantation in a child as medically necessary for the treatment of EITHER of the following:**

- intractable heart failure
- congenital abnormality not amenable to surgical correction

**CIGNA does not cover heart transplantation in an individual with ANY of the following contraindications to transplant surgery because it is considered not medically necessary (this list may not be all-inclusive):**

- malignancy that is expected to significantly limit future survival
- persistent, recurrent or unsuccessfully-treated major or systemic infections
- systemic illness or comorbidities that would be expected to substantially negatively impact the successful completion and/or outcome of transplant surgery
- a pattern of demonstrated noncompliance which would place a transplanted organ at serious risk of failure
- human immunodeficiency virus (HIV) disease unless ALL of the following are noted:
  - CD4 count greater than 200 cells/mm<sup>3</sup>
  - HIV-1 ribonucleic acid (RNA) undetectable
  - stable anti-retroviral therapy for more than three months
  - absence of serious complications associated with or secondary to HIV disease (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidioidomycosis; resistant fungal infections; or Kaposi's sarcoma or other neoplasm)

**Note: Selected candidates may be eligible for multi-organ transplantation. In each case, the candidate should meet all of the criteria for selection for the individual transplant being considered.**

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## General Background

Heart transplantation is the surgical replacement of the damaged or diseased heart of an individual with the viable heart of a human donor. It is the therapy of choice in adults with end-stage heart disease, refractory angina, and malignant ventricular arrhythmias, who have received maximal medical treatment, are unlikely to survive the next 6–12 months and for whom there is no other surgical option (Canter, 2007; Butler, 2004; Fishbein, 2001). Heart transplantation is performed in infants and children with end-stage cardiomyopathy who have become refractory to medical therapy, in individuals with previously repaired or palliated congenital heart disease who have developed ventricular dysfunction or other nonoperable late-term complications, and in patients with complex congenital heart disease (e.g., pulmonary atresia with intact septum and coronary arterial stenoses, some forms of hypoplastic left heart syndrome) for whom standard surgical procedures are extremely high risk (Bernstein, 2007). An obstacle to transplantation is the shortage of donors. The supply of donor hearts has decreased in recent years while the demand has increased significantly.

Advances in immunosuppression, enhanced techniques to detect and treat rejection, and better methods of treating complications have improved the outlook for those receiving heart transplants. According to the Organ Procurement and Transplantation Network (OPTN) 2009 annual report, one-, five-, and ten-year overall recipient survival rates for primary transplantation performed between 1999 and 2008, were 88.0%, 74%, and 55.0%, respectively. The transplant half-life (i.e., the time at which 50% of those transplanted remain alive, or median survival) for the entire cohort of adults and children is currently 10 years, with a half-life of 13 years for those surviving the first year (Taylor, 2007). Risk factors for mortality after transplantation include retransplantation, an intertransplant time (i.e., time between primary and retransplantation) of <180 days, the need for mechanical ventilation or ventricular assist device, use of a female donor, and the overall transplant center volume (Boucek, 2007; Canter, 2008; Mahle, 2008).

Retransplantation accounts for slightly greater than four percent of the total population of individuals undergoing heart transplantation. Within this population common causes of allograft failure are acute rejection, primary graft failure, or transplant arteriopathy (Atluri, 2008). Overall recipient survival outcomes for repeat heart transplantation are 84%, 65.3%, and 42% for one-, five-, and ten years, respectively (OPTN, 2009). Although outcomes are decreased for both children and adults compared to results for primary transplant, retransplantation may be an appropriate intervention for eligible children and adults.

## Contraindications

Many factors affect the outcome of solid organ transplantation. The New York Heart Association (NYHA) Functional Classification of Patients with Heart Disease is a subjective measure of functional capacity which describes the amount of activity an individual can do before the onset of heart failure symptoms is noted. The relation of functional capacity and survival in heart failure is well-established (Costanza, 1995). The criteria are most valuable in predicting the prognosis of Class IV heart failure where the individual has symptoms at rest or with any physical activity (Costanza, 1995).

Appropriate selection is the first step in attaining the best result for each individual. Absolute contraindications to transplantation include malignancy that is expected to significantly limit future survival, persistent, recurrent or unsuccessfully-treated major or systemic infections, systemic illness or co-morbidities that would be expected to substantially negatively impact the successful completion and/or outcome of transplant surgery, a pattern of demonstrated noncompliance which would place a transplanted organ at serious risk of failure, and human immunodeficiency virus (HIV) disease unless ALL of the following are noted: CD4 count greater than 200 cells/mm<sup>3</sup>, HIV-1 ribonucleic acid (RNA) undetectable, stable anti-retroviral therapy for more than three months, absence of serious complications associated with or secondary to HIV disease.

In addition to the absolute contraindications noted, there are many conditions which may increase morbidity and mortality after transplantation. Relative contraindications to heart transplantation include, but are not limited to (McCarthy, 2007; Mehra, 2006; Fishbein, 2001; Steinman, 2001):

- current, ongoing substance abuse, including tobacco, alcohol and narcotic/other addictive pain medications
- cerebrovascular disease or accident, or progressive neuropathy or myopathy that is not amenable to rehabilitation
- body mass index (BMI) <17 or >33
- any active medical process that is currently not optimally treated and/or stable and that is likely to result in end-organ damage or medical emergency without appropriate management, such as active peptic ulcer disease, diverticular disease, active hepatitis, cholecystitis, pancreatitis, hypertension, autoimmune disease, cytopenia
- hepatic fibrosis or cirrhosis
- hepatitis C with biopsy-proven, histologic evidence of hepatic disease
- uncorrected abdominal aortic aneurysm >4 centimeters
- diabetes mellitus with end-organ damage, such as neuropathy, nephropathy or retinopathy
- advanced age
- peripheral vascular disease not amenable to surgical or percutaneous therapy
- asymptomatic carotid stenosis >75% or symptomatic carotid stenosis of less severity
- ankle brachial index <0.7 or substantial risk of limb loss
- systemic infection making immune response risky, including human immunodeficiency virus (HIV), hepatitis B virus (HBV) and cytomegalovirus (CMV) of the donor
- severe obstructive or restrictive lung disease, as evidenced by pulmonary function testing (FEV1 <1.51 liters)
- recent pulmonary embolism or infarction
- irreversible pulmonary hypertension, as evidenced by:
  - elevated pulmonary artery pressures (>65 mmHg) despite vasodilators or inotropes
  - elevated transpulmonary gradient (>15 mmHg) despite treatment
  - elevated pulmonary vascular resistance (PVR) (>six Wood units) despite vasodilators or inotropes
- in children, an elevated pulmonary vascular resistance index >six Woods units requires additional investigation and optimization of the medical regimen (Addonizio, 2001)

### **Literature Review**

No prospective randomized study comparing heart transplantation to optimal medical therapy has been reported; however, several retrospective reviews and database analyses have demonstrated improved long-term outcomes with heart transplantation for selected individuals (Deuse, 2008; Tjang, 2008; Weiss, 2008). Heart transplantation is considered a standard of care for selected individuals.

### **Professional Societies/Organizations**

**American College of Cardiology, American Heart Association, American College of Chest Physicians, International Society for Heart and Lung Transplantation:** Updated Practice Guidelines for the Diagnosis and Management of Chronic Heart Failure in the Adult (2005; focused update 2009) note that heart transplantation is an appropriate therapy for the management of refractory heart failure. Indications for heart transplantation focus on the identification of patients with severe functional impairment or dependence on intravenous inotropic agents. Absolute indications in appropriate individuals include heart transplantation for hemodynamic compromise due to heart failure, refractory cardiogenic shock, documented dependence on IV inotropic support to maintain adequate organ perfusion, peak venous oxygenation (VO<sub>2</sub>) <10mL per kg per min with achievement of anaerobic metabolism, severe symptoms of ischemia that consistently limit routine activity and are not amenable to coronary artery bypass surgery or percutaneous coronary intervention, and recurrent symptomatic ventricular arrhythmias refractory to all therapeutic modalities. Less common indications for cardiac transplantation include recurrent, life-threatening ventricular arrhythmias or angina that is refractory to all currently available treatments (Hunt, 2005). A focused update incorporated into the 2005 Practice Guidelines discussed above notes that referral for cardiac transplantation in potentially eligible patients is recommended for patients with refractory end-stage heart failure (Hunt, 2009).

**American Heart Association Council on Cardiovascular Disease in the Young, the Councils on Clinical Cardiology, Cardiovascular Nursing and Cardiovascular Surgery and Anesthesia, and the Quality of Care and Outcomes Research Interdisciplinary Working Group:** Canter et al. (2007) published a joint statement on behalf of these professional societies that notes several recommendations for the use of heart transplantation for the treatment of heart disease in children:

- as therapy for children with heart failure associated with systemic ventricular function in patients with cardiomyopathies or previously repaired or palliated congenital heart disease
- as therapy for children with heart failure associated with severe limitation of exercise and activity
- as therapy for children with heart failure associated with systemic ventricular dysfunction in patients with cardiomyopathies or previously repaired or palliated congenital heart disease when associated with significant growth failure attributable to the heart disease
- as therapy for children with heart failure in pediatric restrictive cardiomyopathy disease associated with reactive pulmonary hypertension
- in the presence of other indications for heart transplantation, this therapy is feasible in children with heart disease and an elevated pulmonary vascular resistance index > six Woods units/m and/or a transpulmonary pressure gradient > 15 mm Hg if inotropic support or pulmonary vasodilators can result in a decrease of these values.

Additionally, the statement notes that heart retransplantation is indicated in children:

- with abnormal ventricular function and at least moderate graft vasculopathy
- with normal ventricular function and at least moderate graft vasculopathy

The statement also notes that retransplantation should not be performed during an episode of ongoing acute allograft rejection, even in the presence of graft vasculopathy and that retransplantation is not efficacious when performed during the first six months after primary transplantation.

**Canadian Cardiovascular Society Consensus (2009):** Haddad et al. notes that “Cardiac transplantation is the treatment of choice for patients who have severe end-stage heart failure despite maximal medical therapy and/or complex congenital heart disease not amenable to surgical palliation at reasonable risk. In general, patients with extracardiac disease that would significantly reduce their expected lifespan, or that would be exacerbated by the post-transplant use of immunosuppressive agents, are not candidates for transplantation, nor are patients without significant rehabilitation potential.”

## Summary

Heart transplantation is an effective treatment for selected individuals with advanced heart failure, malignant ventricular arrhythmias, and refractory angina that is unresponsive to optimal medical or surgical therapy. It is also an effective therapy for children with intractable heart failure or congenital abnormalities not amenable to surgical correction.

## Coding/Billing Information

**Note:** This list of codes may not be all-inclusive.

**Covered when medically necessary:**

CPT®*	Description
33940	Donor cardiectomy (including cold preservation)
33944	Backbench standard preparation of cadaver donor heart 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

HCPCS Codes	Description
S2152	Solid organ(s), complete or segmental, single organ or combination of organs; deceased or living donor(s), procurement, transplantation, and related complications including: drugs; supplies; hospitalization with outpatient follow-up; medical/surgical, diagnostic, emergency, and rehabilitative services; and the number of days of pre- and post-transplant care in the global definition

ICD-9-CM Diagnosis Codes	Description
410.00-411.89	Acute myocardial infarction and other acute and subacute forms of ischemic heart disease
413.9	Other and unspecified angina pectoris
414.00-414.07	Coronary atherosclerosis
414.8	Other specified forms of chronic ischemic heart disease
414.9	Chronic ischemic heart disease, unspecified
422.90-422.99	Other and unspecified acute myocarditis
425.0	Endomyocardial fibrosis
425.1	Hypertrophic obstructive cardiomyopathy
425.4	Other primary cardiomyopathies
427.0-427.9	Cardiac dysrhythmias
428.0- 428.9	Heart failure
745.0-745.9	Bulbus cordis anomalies of cardiac septal closure
746.00-746.9	Other congenital anomalies of heart
785.51	Cardiogenic shock
996.83	Complication of transplanted organ, heart

\*Current Procedural Terminology (CPT®) © 2010 American Medical Association: Chicago, IL.

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## Policy History

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<b>Pre-Merger Organizations</b>	<b>Last Review Date</b>	<b>Policy Number</b>	<b>Title</b>
CIGNA HealthCare	8/15/2008	0129	Heart Transplantation
Great-West Healthcare	4/07/2006	95.218.06	Transplantation, Heart-Adult
	4/07/2006	95.219.06	Transplantation, Heart-Pediatric

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