Healthy Blue

Medical Policy

Subject:	Heart Transplantation		
Document #:	TRANS.00033	**Publish Date:**	12/16/2020
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Description/Scope

This document addresses cardiac transplantation, a therapeutic modality for individuals with end-stage heart disease, characterized by cardiac failure that does not respond to standard, optimal medical or surgical treatments.

Note: Please see TRANS.00026 Heart/Lung Transplantation for additional information.

Position Statement

Medically Necessary:

Heart transplantation is considered **medically necessary** in carefully selected individuals when the following clinical indications **and** the General Individual Selection criteria below are met.

Adult Clinical Indications* - Adults with end-stage, irreversible, refractory, symptomatic heart failure requiring *maximal* continuous medical or mechanical support must have:

A. A low functional status; **and**
B. A poor probability of survival; **and**
C. **ONE** of the following underlying conditions:
   1. Supported by a mechanical circulatory support device; **or**
   2. Supported by an intra-aortic balloon pump (IABP); **or**
   3. Refractory cardiogenic shock; **or**
   4. Dependency on intravenous (IV) inotropic support to maintain adequate organ perfusion; **or**
   5. Maximal VO_2 less than or equal to 10 ml/kg/min with achievement of anaerobic metabolism; **or**
   6. Maximal VO_2 greater than 10 and less than 15 ml/kg/min (or 55% of predicted) and major limitation of the individual's activities; **or**
   7. Severe ischemia consistently limiting routine activity not amenable to bypass surgery or percutaneous coronary intervention (PCI); **or**
   8. Recurrent unstable ischemia not amenable to bypass surgery or percutaneous coronary intervention (PCI); **or**
   9. Recurrent symptomatic ventricular arrhythmias refractory to ALL therapeutic modalities; **or**
   10. Ischemic cardiomyopathy not amenable to medical therapy or revascularization procedures.

Pediatric Clinical Indications* - Heart transplant is an accepted treatment option for selected children with end-stage heart disease characterized by intractable symptoms and heart failure that cannot be treated with conventional medical or surgical methods. Children must have:

A. Low cardiac output; **and**
B. **ONE** of the following conditions:
    1. Intractable heart failure not amenable to medical or surgical interventions; **or**
    2. Complex congenital heart disease not amenable to surgical repair or palliation or for which the surgical procedure carries a higher risk of mortality than transplantation; **or**
    3. Heart disease with reactive pulmonary hypertension and a potential of developing fixed, irreversible increased pulmonary vascular resistance (PVR) that would preclude a future orthotopic heart transplantation; **or**
    4. Heart disease associated with near sudden death; **or**
    5. Life-threatening arrhythmias untreatable with medications or an implantable defibrillator.

***Note:** For multi-organ transplant requests, criteria must be met for each organ requested. In those situations, an individual may present with a concurrent medical condition which would be considered an exclusion or a comorbidity that would preclude a successful outcome, but would be treated with the other organ transplant. Such cases will be reviewed on an individual basis for coverage determination to assess the member's candidacy for transplantation.

Heart Retransplantation

Retransplantation in individuals with graft failure of an initial heart transplant, due to either technical reasons or hyperacute rejection is considered **medically necessary.**

Retransplantation in individuals with chronic rejection, moderate graft vasculopathy or recurrent disease is considered **medically necessary** when the individual meets general individual selection criteria as defined below.

Investigational and Not Medically Necessary:

A heart transplantation is considered **investigational and not medically necessary** when the above criteria are not met.

General Individual Selection Criteria

In addition to having end-stage heart disease, the member must not have a contraindication to transplantation, as defined by the American Society of Transplantation (Steinman, 2001) and the International Society for Heart and Lung Transplantation (Mehra, 2016) as listed below.

Relative Contraindications for Transplant *Recipients* include, but are not limited to, the following:
A. Pulmonary hypertension that is fixed as evidenced by either:

1. Pulmonary vascular resistance (PVR) greater than 5 Wood units; **or**
2. Trans-pulmonary gradient (TPG) greater than or equal to 16 mm/Hg.

Absolute Contraindications for Transplant *Recipients* include, but are not limited to, the following:

A. Metastatic cancer;
B. Ongoing or recurring infections that are not effectively treated;
C. Serious cardiac or other ongoing insufficiencies that create an inability to tolerate transplant surgery;
D. Serious conditions that are unlikely to be improved by transplantation as life expectancy can be finitely measured;
E. Active, systemic lupus erythematosus or sarcoid with multisystem involvement;
F. Any systemic condition with a high probability of recurrence in the transplanted heart;
G. Demonstrated patient noncompliance, which places the organ at risk by not adhering to medical recommendations;
H. Potential complications from immunosuppressive medications are unacceptable to the patient;
I. Acquired immune deficiency syndrome (AIDS) (diagnosis based on Centers for Disease Control and Prevention [CDC] definition of CD4 count, 200 cells/mm^3) unless the following are noted:
   1. CD4 count greater than 200 cells/mm^3 for greater than 6 months;
   2. HIV-1 RNA undetectable;
   3. On stable anti-retroviral therapy greater than 3 months;
   4. No other complications from AIDS (for example, opportunistic infection, including aspergillus, tuberculosis, coccidioidomycosis, resistant fungal infections, Kaposi's sarcoma or other neoplasm);
   5. Meeting all other criteria for heart transplantation.

Rationale

Heart transplantation is a standard treatment for individuals with end-stage heart disease that is not amenable to medical or surgical therapies. In the 2013 American College of Cardiology Foundation (ACCF)/American Heart Association (AHA) guideline for the management of heart failure authors reported:

> Cardiac transplantation is considered the gold standard for the treatment of refractory end-stage HF. Since the first successful cardiac transplantation in 1967, advances in immunosuppressive therapy have vastly improved the long-term survival of transplant recipients with a 1, 3, and 5 year post-transplant survival rate of 87.8%, 78.5%, and 71.7% in adults, respectively. Similarly, cardiac transplantation has been shown to improve functional status and heart failure with reduced ejection fraction (HRQOL) (Yancy, 2013).

The previous guidelines for heart transplantation from the International Society for Heart and Lung Transplantation (ISHLT) were developed before the incorporation of β-blocker and device therapies for the treatment of late or end-stage heart disease (Mehra, 2006). Mehra and colleagues (2006) reported early studies showing a significant survival benefit with heart transplantation in adults with a peak VO_2 less than 14 ml/kg/min when compared to individuals who were not considered eligible for transplantation and were maintained on a medical regimen. A subset of individuals with a peak VO_2 less than 10 ml/kg/min who achieved anaerobic threshold had a lower

survival rate when compared to individuals with a VO_2 between 10-14 ml/kg/min. Medical therapies utilized in adults for treatment of heart disease have also been incorporated into the pediatric population. In addition, there have been significant improvements in overall survival for staged palliative surgeries for left hypoplastic heart disease (Canter, 2007). Therefore, the heart transplant listing criteria for adults and pediatrics were re-evaluated.

Over time complex congenital heart disease may be worsened with specific anatomic and physiological conditions. These individuals are eligible for heart transplantation and the conditions described by Canter and colleagues (2007) include, but are not limited to:

- Severe stenosis or atresia in proximal coronary arteries;
- Moderate to severe stenosis or insufficiency of the atrioventricular or systemic semilunar valve(s);
- Severe ventricular dysfunction;
- Pulmonary hypertension and a potential risk of developing fixed, irreversible elevated PVR that may preclude future orthotopic heart transplant;
- Severe aortic or systemic AV valve insufficiency not amenable to surgical correction;
- Severe arterial oxygen desaturation;
- Persistent protein-losing enteropathy intractable to optimal medical-surgical therapies.

Cardiopulmonary exercise test results are routinely utilized to determine transplant candidacy. Testing is limited to individuals older than 7-8 years of age (Canter, 2007). Maximal VO_2 describes the maximum amount of oxygen utilized while exerting maximal physical activity per kilogram of body weight per minute. The testing is usually performed on a treadmill or on a cycloergometer. There are different calculators to estimate VO_2 max. Individuals that are physically fit have higher VO_2 max values and can perform more intense exercises. VO_2 max is properly determined by the Fick Equation: $VO_2max = Q (CaO_2 - CvO_2)$ where Q is cardiac output, CaO_2 is arterial oxygen content, and CvO_2 is venous oxygen content. The average young untrained male will have a VO_2 max of approximately 45 ml/min/kg. The average young untrained female will score a VO_2 max of 38 ml/min/kg. These scores can improve with training and generally decrease with age.

Post-transplant morbidity and mortality are frequently caused by right heart failure. Recommendations by the International Society for Heart and Lung Transplantation (ISHLT) include a pre-transplant vasodilator challenge to be administered if either pulmonary vascular resistance (PVR) is greater than 3 Wood units or the transpulmonary gradient (TPG) is greater than or equal to 15. Despite the lack of absolute cutoff values that would contraindicate transplantation, analyses of the ISHLT registry demonstrated incremental risks as PVR increased. Survival comparison of those with 1-3 Wood units had better outcomes when compared to individuals with a PVR of greater than 5 Wood units. Relative contraindications to heart transplant include PVR greater than 5 Wood units or TPG greater than 16-20 mm Hg or PVR index is greater than 6 (Canter, 2007; Mehra, 2016).

Coronary artery vasculopathy (CAV) is a diffuse disease process that results in progressive coronary artery atherosclerosis and is a threat to long-term survival. CAV is the most common cause of complications and death after the first year post-heart transplant. Angiographically confirmed graft vasculopathy results in a poor prognosis. Graft loss or death within 2 years of diagnosis was noted in 24% of individuals with any degree of vasculopathy and 50% of individuals with moderate to severe graft vasculopathy. Canter and colleagues (2007) reported a 2-3% annual risk of death or graft loss, with 70% of the events due to cardiac failure resulting from graft vasculopathy,

rejection or a combination of both. A pediatric study resulted in similar 3-year survivals of 82% compared with 77% in re-transplantations versus primary transplantations (Canter, 2007). There have been various hypotheses and studies to determine the etiology, diagnosis, prevention and treatment of CAV. Despite therapeutic interventions, CAV may result in end-stage heart failure requiring a retransplantation. Because of limited donors and the mortality rates with CAV, ongoing clinical studies are focused on preventive therapies to reduce the incidence and severity of CAV (Boucek, 2007; Kobashigawa, 2000; Ross, 2007).

Groetzner and colleagues (2005) reported on 50 pediatric heart transplantations performed between 1988 and 2002. Actuarial survival rates at 1, 5 and 10 years were 86%, 80% and 80% for individuals transplanted thru 1995. With the addition of newer drugs such as the calcineurin inhibitor tacrolimus, immunosuppressant mycophenolate mofetil (MMF), and improved prophylactic therapies, the actuarial survival rates improved to 92% for both 1 and 5 years for individuals transplanted after 1995. A 6% perioperative mortality rate was a result of primary graft failure. Acute rejections resulted in death for 12% of individuals. Rejection and infections continue to be serious complications for pediatric heart transplantation. Additional studies need to be continued to determine the long-term effects of immunosuppressants, graft vessel disease, neoplastic disorders, renal complications and quality of life. The shortage of donor organs limits pediatric heart transplantation to individuals that have medically and surgically untreatable heart failure without therapeutic options (Groetzner, 2005).

Background/Overview

Heart transplants involve the removal of either all or part of a cadaver heart and its implantation into a recipient. There are two types of cardiac transplant: orthotopic and heterotopic. Orthotopic transplant is the more common of the two methods and involves replacing the recipient heart with the donor heart implanting the ventricles of the donor heart onto the right atria and main arteries of the recipient's heart. Heterotopic transplants involve placing the entire donor heart into the chest cavity and surgically attaching it to the recipient's entire heart.

In contrast to the 1980s when the majority of heart transplant recipients were sick but stable individuals waiting at home, the majority of heart transplant recipients are now hospitalized Status 1A or 1B individuals at the time of transplant. This shift has occurred due to the increasing demand on the scarce resource of donor organs resulting in an increased waiting time for donor organs. Individuals initially listed as a Status 2 candidate may deteriorate to a Status 1A or 1B candidate before a donor organ becomes available. At the same time, medical therapy of heart failure has improved (particularly with the advent of ACE inhibitors), making it imperative that heart transplantation be limited to those individuals who have truly exhausted medical therapy and thus are likely to derive the maximum benefit from heart transplantation. Consequently, there has been a search to identify prognostic criteria that could identify such individuals. As noted in the American College of Cardiology (ACC) criteria (Hunt, 2009), the VO_2 max serves as a critical objective criterion. The VO_2 max, measured during maximal exercise, reflects the functional reserve of the heart. Studies have suggested that transplantation can be safely deferred in those individuals with a VO_2 max of greater than 14 ml/kg/min. The importance of the VO_2 max has also been emphasized by an American Heart Association Scientific Statement addressing heart transplant candidacy (Costanzo, 1995; Mudge, 1995). In past years, a left ventricular ejection fraction of less than 20% or an NYHA Class III or IV status may have been used to determine transplant candidacy. However, as indicated by the ACC criteria, these measurements are no longer considered adequate to identify transplant candidates. These

measurements may be used to identify individuals for further cardiovascular workup, but should not be the sole criteria for transplant.

The limiting factor for heart transplantation is the short supply of donor organs. The procurement and distribution of heart organs for transplantation in the U.S. is under the direction of United Network for Organ Sharing (UNOS). A national database of transplant candidates, donors, recipients, and donor-recipient matching and histocompatibility is maintained by UNOS. A policy for allocation of heart and heart-lung organs prioritizes donor heart organs according to the principles of medical urgency (UNOS, 2020). The careful selection of candidates utilizing specific selection criteria has steadily improved the survival rates for those that have undergone heart transplantation. The best available evidence, collected from retrospective registry data on heart transplantation in the United States, is based on UNOS data collected from 2008-2015 which reports 1-year, 3-year and 5-year survival data (90.9%, 85.5%, 78.6%). The number of heart transplant candidates and heart transplants performed in the United States continues to rise annually, with 3440 heart transplants performed in 2018 (Colvin, 2018). Currently to date in 2020 there are 3502 candidates on the waitlist for heart transplant in the United States, with 3552 heart transplants performed in 2019 and 2427 performed to date in 2020.

Definitions

End-stage heart failure: In people with heart failure, the body does not receive an adequate supply of oxygen. As a result, they can feel weak, fatigued or short of breath resulting in limited functional capacity. Everyday activities such as walking, climbing stairs, carrying groceries and yard work can become quite difficult. In end-stage heart failure, the heart is so weakened the individual will die without a heart transplant.

Heart transplant: Removal of an individual's heart and replacing it with a donor heart.

Mechanical circulatory support device (MCSD): An implanted ventricular assist device or percutaneous ventricular assist device.

New York Heart Association (NYHA) definitions:

The NYHA classification of heart failure is a tiered system that categorizes subjects based on subjective impression of the degree of functional compromise; the class III and IV NYHA functional classes are as follows:

- Class III. Patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity causes fatigue, palpitation, dyspnea (difficulty breathing) or anginal (chest) pain.
- Class IV. Patients with cardiac disease resulting in the inability to carry on any physical activity without discomfort. Symptoms of heart failure or the anginal (chest) syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increased.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:

CPT	
00580	Anesthesia for heart transplant or heart/lung transplant
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
ICD-10 Procedure	
02YA0Z0	Transplantation of heart, allogeneic, open approach
02YA0Z1	Transplantation of heart, syngeneic, open approach
ICD-10 Diagnosis	
	All diagnoses

When services are Investigational and Not Medically Necessary:
For the codes listed above when criteria are not met, or when the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

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4. United Network for Organ Sharing. Available at: http://www.unos.org/. Accessed on October 8, 2020.

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Document History

Status	Date	Action
Reviewed	11/05/2020	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Rationale, References and Websites sections.
Revised	11/07/2019	MPTAC review. Clarified MN clinical indication for heart transplantation in adults requiring mechanical support, changed "presence of" an implanted VAD or IABP to "supported by" a mechanical circulatory support device or IABP. Updated Background, Definitions, References and Websites sections.
Reviewed	01/24/2019	MPTAC review. Updated Background, References and Websites sections.
Reviewed	03/22/2018	MPTAC review. Updated formatting in MN position statement. Updated Background, References and Websites sections.
Reviewed	11/02/2017	MPTAC review. The document header wording updated from "Current Effective Date" to "Publish Date." Updated Rationale, Background, References and Websites sections.
Reviewed	11/03/2016	MPTAC review. Updated formatting in Position Statement section. Updated Rationale, Background, References and Websites sections.
Revised	11/05/2015	MPTAC review. Defined abbreviation in investigational and not medically necessary statement. Updated Background, References and Websites sections. Removed ICD-9 codes from Coding section.
Reviewed	11/13/2014	MPTAC review. Updated Description. Rationale, Background, References and Websites sections.
Reviewed	11/14/2013	MPTAC review. Updated Rationale, Background, References and Websites.
Reviewed	11/08/2012	MPTAC review. Updated Definitions, References and Websites.
Revised	02/16/2012	MPTAC review. Revised adult heart transplant medically necessary statement to include presence of intra-aortic balloon pump (IABP) as an underlying condition. Updated Background, References and Websites.
Reviewed	02/17/2011	MPTAC review. Removed "and/or" phrase from medically necessary statement. Rationale updated. Updated References and Websites.
Revised	02/25/2010	MPTAC review. Clarified medically necessary statement and adult medically necessary criteria for heart transplant. References updated.
Reviewed	02/26/2009	MPTAC review. References updated.

Reviewed	02/21/2008	MPTAC review. No change in position statement. Updated references. The phrase "investigational/not medically necessary" was clarified to read "investigational and not medically necessary" at the November 29, 2007 MPTAC meeting.
Revised	03/08/2007	MPTAC review. Medical necessity criteria updated to align with ACC, AHA and ISHLT criteria. Added retransplantation criteria. Updated references, background, websites and coding.
Reviewed	03/23/2006	MPTAC review. No changes to criteria. References were updated to include the 2005 updated ACC/AHA Guideline for the Diagnosis and Management of Chronic Heart Failure in the Adult.
	11/18/2005	Added reference for Centers for Medicare and Medicaid Services (CMS) – National Coverage Determination (NCD).
Revised	04/28/2005	MPTAC review. Revision based on: Pre-merger Anthem and Pre-merger WellPoint Harmonization.

Pre-Merger Organizations	**Last Review Date**	**Document Number**	**Title**
Anthem, Inc.	10/09/2001	TRANS.00005H Archived	Heart Transplant
WellPoint Health Networks, Inc.	03/11/2004	7.04.02	Heart Transplantation-Adult
	03/11/2004	7.04.03	Heart Transplantation-Pediatric