Anthem

Medical Policy

Subject: Heart Transplantation
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Description/Scope

This document addresses cardiac transplantation, a therapeutic modality for individuals with end-stage heart disease, characterized by heart failure (also known as cardiac failure or HF) 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 refractory end-stage HF that is not amenable to medical or surgical therapies. According to Heidenreich and colleagues (2022), the long-term survival of adult transplant recipients between 2011 and 2013 at 1, 3, and 5 years post-transplant is 90.3%, 84.7%, and 79.6%, respectively. Similarly, cardiac transplantation has been shown to improve functional status and health-related quality of life.

The 2022 American College of Cardiology (ACC)/American Heart Association (AHA)/Heart Failure Society of America (HFSA) published guidelines for the management of HF replaces the 2013 ACCF/AHA guidelines for the management of HF and the 2017 ACC/AHA/HFSA focused update of the 2013 guidelines. (Heidenreich, 2022). In the 2022 guidelines the committee provides recommendation (category 1c) for heart transplantation to improve survival and quality of life in eligible individuals with advanced stage D HF refractory to guideline directed medical treatment (GDMT), device, and surgical management. Heart transplantation provides a mortality and morbidity benefit to selected individuals with stage D HF.

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 (2016) 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. 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 natal male will have a VO_2 max of approximately 45 ml/min/kg. The average young untrained natal 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 HF. 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 (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 heart 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 HF 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 HF 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 HF 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 a 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, 2023). 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 2008-2019 which reports 1-year, 3-year and 5-year survival data (90.9%, 87.6%, 77.3%). The number of heart transplant candidates and heart transplants performed in the United States continues to rise annually, with 3552 heart transplants performed in 2019 (Colvin, 2021).

Heart transplants were the third most common transplant procedure with 3817 transplants performed in the United States in 2021. As of October 2022, there were 3370 candidates on the waitlist for heart transplant and 2644 individuals who underwent heart transplantation in 2022.

In March 2023, the Organ Procurement and Transplantation Network (OPTN) changed the policy to expand the eligibility to pediatric heart status 1A and B candidates, who are registered on the waiting list prior to turning age 2, to accept incompatible blood type (ABOi) donors.

In recent years, the discussion of heart transplantation as a treatment for cardiomyopathy caused by amyloidosis has garnered interest. Cardiac amyloidosis causes restrictive cardiomyopathy, progressive heart failure, and death. Heart transplantation outcomes have been poorer in individuals with cardiac amyloidosis due to the systemic nature of the condition. Suppressive therapies for light chain amyloidosis (AL) may improve outcomes. Barrett and colleagues (2020) reported a retrospective, single center study of heart transplantation outcomes in 31 individuals with cardiac amyloidosis (13 with AL, and 18 with transthyretin [ATTR] amyloidosis). Screening included evaluation for extracardiac amyloidosis with organ specific biopsies, and extracardiac amyloid deposits constituted an absolute contraindication. In individuals with vascular or mucosal amyloid positive gastrointestinal biopsy, transplantation candidacy was evaluated by clinical symptoms. Individuals were considered for transplantation if there was no evidence of dysmotility, bleeding, or malabsorption. Pre-transplantation response to light chain reducing therapies in AL amyloidosis was not an absolute requirement for transplantation. Post-transplantation immunosuppression regimens were followed. Autologous stem cell transplants were performed in select participants with AL amyloidosis once they achieved clinical stability following the transplant, but no sooner than 6 months post-heart transplantation. The results demonstrated that post-transplantation outcomes were similar between the AL and ATTR groups, including post-transplantation infection and organ rejection. Two participants had difficulty with post-transplantation hemostasis, and 5 developed post-transplantation renal dysfunction that required renal replacement therapy. One participant with gastrointestinal amyloid deposits developed a post-operative ileus, which resolved. Of the 2 participants with renal amyloidosis, 1 developed progressive renal dysfunction that required dialysis 7 years after transplantation. There were 4 deaths after transplantation, but none were determined to be due to amyloidosis or amyloidosis therapy complications. There were no differences in mortality between the 31 participants and 599 individuals without amyloidosis who underwent heart transplantation for all other indications at the same facility. The authors concluded that in carefully selected individuals with AL and ATTR cardiac amyloidosis, the results were similar in both post-transplantation outcomes and survival compared to individuals without amyloidosis who received transplantation for all other conditions. These results are promising; however, the study was limited by its small size and single center transplant practices. Treatment practices and transplant eligibility policies can vary between institutions and could lead to different results, therefore larger studies are needed to confirm the outcomes.

In 2023 the ACC published the "Expert Consensus Decision Pathway on Comprehensive Multidisciplinary Care for the Patient With Cardiac Amyloidosis." The consensus supports heart transplant in some individuals with cardiac amyloidosis:

> In select patients with ATTR-CM and AL-CM with advanced/stage D HF, heart transplantation may be an option, and the current adult donor allocation system provides priority as Status 4 to amyloid CM, given the lack of durable (MCS) support options. The traditional signs of advanced HF apply in patients with cardiac amyloidosis and should be recognized as triggers for a discussion of prognosis and advanced HF therapies that incorporates the patient's

goals, values, and preferences.

The ACC acknowledges that no single test can identify which individuals may be candidates for advanced HF therapies; multiple factors including the history, physical examination, laboratory testing, and imaging studies must be considered together to identify those at greatest risk of future decompensation and those who will derive the greatest benefit.

Definitions

End-stage heart failure: In people with HF, 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 HF, 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 HF 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 HF 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
33929	Removal of a total replacement heart system (artificial heart) for heart transplant [add-on code with 33945]
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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Websites for Additional Information

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Document History

Status	Date	Action
	04/10/2024	Revised Coding section; added CPT 33929 previously addressed in SURG.00145.
Reviewed	11/09/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Background/Overview, References and Website sections.
Reviewed	11/10/2022	MPTAC review. Updated Rationale, Background, References and Websites sections.
Reviewed	11/11/2021	MPTAC review. Updated Background, References and Websites sections.
Reviewed	11/05/2020	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

Applicable to Commercial HMO members in California: When a medical policy states a procedure or treatment is investigational, PMGs should not approve or deny the request. Instead, please fax the request to Anthem Blue Cross Grievance and Appeals at fax # 818-234-2767 or 818-234-3824. For questions, call G&A at 1-800-365-0609 and ask to speak with the Investigational Review Nurse.

Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The member’s contract benefits in effect on the date that services are rendered must be used. Medical Policy, which addresses medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.