



MASSACHUSETTS

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Medical Policy

Heart Transplant

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Policy Number: 197

BCBSA Reference Number: 7.03.09

NCD/LCD: NA

Related Policies

- Heart-Lung Transplant, [#269](#)
- Total Artificial Hearts and Ventricular Assist Devices, [#280](#)
- Laboratory Tests for Heart Transplant Rejection, [#530](#)
- Immune Cell Function Assay in Solid Organ Transplantation, [#182](#)

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO BlueSM and Medicare PPO BlueSM Members

Human heart transplantation may be considered **MEDICALLY NECESSARY** for selected adults and children with end-stage heart failure when any one of the following criteria are met:

Adult Patients

1. Accepted Indications for Transplantation
 - a. Hemodynamic compromise due to heart failure demonstrated by any of the following 3 bulleted items:
 - Maximal Vo_2 (oxygen consumption) <10 mL/kg/min with achievement of anaerobic metabolism
 - Refractory cardiogenic shock
 - Documented dependence on intravenous inotropic support to maintain adequate organ perfusion
 - or
 - b. Severe ischemia consistently limiting routine activity not amenable to bypass surgery or angioplasty, or
 - c. Recurrent symptomatic ventricular arrhythmias refractory to ALL accepted therapeutic modalities.
2. Probable Indications for Cardiac Transplantation
 - a. Maximal Vo_2 <14 mL/kg/min and major limitation of the patient's activities, or

- b. Recurrent unstable ischemia not amenable to bypass surgery or angioplasty, or
 - c. Instability of fluid balance/renal function not due to patient noncompliance with regimen of weight monitoring, flexible use of diuretic drugs, and salt restriction.
3. The following conditions are inadequate indications for transplantation unless other factors as listed above are present:
- a. Ejection fraction <20%
 - b. History of functional class III or IV symptoms of heart failure
 - c. Previous ventricular arrhythmias
 - d. Maximal $\text{Vo}_2 > 15 \text{ mL/kg/min}$.

Pediatric Patients

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

- Continuous infusion of intravenous inotropic agents, or
- Mechanical ventilatory support, or
- Mechanical circulatory support, or

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

- Severe limitation of exercise and activity (if measurable, such patients would have a peak maximum oxygen consumption <50% predicted for age and sex); or
- Cardiomyopathies or previously repaired or palliated congenital heart disease and growth failure attributable to the heart disease; or
- Near sudden death and/or life-threatening arrhythmias untreatable with medications or an implantable defibrillator; or
- Restrictive cardiomyopathy with reactive pulmonary hypertension; or
- Reactive pulmonary hypertension and risk of developing fixed, irreversible elevation of pulmonary vascular resistance that could preclude orthotopic heart transplantation in the future; or
- Anatomical and physiological conditions likely to worsen the natural history of congenital heart disease in infants with a functional single ventricle; or
- Anatomical and physiological conditions that lead to heart transplantation without systemic ventricular dysfunction.

Heart retransplantation after a failed primary heart transplant may be considered **MEDICALLY NECESSARY** in patients who meet criteria for heart transplantation.

Heart transplantation is **INVESTIGATIONAL** in all other situations.

In addition to the above information, we do not cover heart transplantation when any of the following conditions are present:

- Known current malignancy, including metastatic cancer
- Recent malignancy with high risk of recurrence
 - Note: the assessment of risk of recurrence for a previously treated malignancy is made by the transplant team; providers must submit a statement with an explanation of why the patient with a recently treated malignancy is an appropriate candidate for a transplant.
- Untreated systemic infection making immunosuppression unsafe, including chronic infection
- Other irreversible end-stage disease not attributed to heart or lung disease
- History of cancer with a moderate risk of recurrence
- Systemic disease that could be exacerbated by immunosuppression
- Psychosocial conditions or chemical dependency affecting ability to adhere to therapy
- Pulmonary hypertension that is fixed as evidenced by pulmonary vascular resistance (PVR) greater than 5 Wood units, or transpulmonary gradient (TPG) greater than or equal to 16 mm/Hg despite treatment*

- Severe pulmonary disease despite optimal medical therapy, not expected to improve with heart transplantation.*

*Some patients may be candidates for combined heart-lung transplantation (See policy #269).

Prior Authorization Information

Pre-service approval is required for all inpatient services for all products.

See below for situations where prior authorization may be required or may not be required for outpatient services.

Yes indicates that prior authorization is required.

No indicates that prior authorization is not required.

N/A indicates that this service is primarily performed in an inpatient setting.

	Outpatient
Commercial Managed Care (HMO and POS)	N/A
Commercial PPO and Indemnity	N/A
Medicare HMO BlueSM	N/A
Medicare PPO BlueSM	N/A

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

CPT Codes

CPT codes:	Code Description
33945	Heart transplant, with or without recipient cardiectomy

ICD-10 Procedure Codes

ICD-10-PCS procedure codes:	Code Description
02YA0Z0	Transplantation of Heart, Allogeneic, Open Approach
02YA0Z1	Transplantation of Heart, Syngeneic, Open Approach

Description

HEART FAILURE

In the United States, approximately 6.5 million people 20 years of age and older have heart failure and 309,000 die each year from this condition. The reduction of cardiac output is considered to be severe when systemic circulation cannot meet the body's needs under minimal exertion.

Heart failure may be due to a number of differing etiologies, including ischemic heart disease, cardiomyopathy, or congenital heart defects. The leading indication for a heart transplant has shifted over time from ischemic to nonischemic cardiomyopathy. From 2009 to 2014, nonischemic cardiomyopathy was the dominant underlying primary diagnosis among patients 18 to 39 years (64%) and 40 to 59 years

(51%) undergoing transplant operations. Ischemic cardiomyopathy was the dominant underlying primary diagnosis among the heart transplant recipients 60 to 69 years (50%) and 70 years and older (55%). Overall, ischemic cardiomyopathy is the underlying heart failure diagnosis in approximately 40% of men and 20% of women who receive a transplant. Approximately 3% of the heart transplants during this time period were in adults with congenital heart disease.

Treatment

Innovations in medical and device therapy for patients with advanced heart failure have improved the survival of patients awaiting heart transplantation. The demand for heart transplants far exceeds the availability of donor organs, and the length of time patients are on the waiting list for transplants has increased. According to data from the Organ Procurement and Transplantation Network, in 2017, a total of 3244 heart transplants were performed in the United States. As of July 2018, there were 4003 patients on the waiting list for a heart transplant. The chronic shortage of donor hearts has led to the prioritization of patients awaiting transplantation to ensure greater access for patients most likely to derive benefit. Prioritization criteria are issued by the Organ Procurement and Transplantation Network and fulfilled through a contract with the United Network for Organ Sharing.

From 2008 to 2015, approximately 4% of heart transplants were repeat transplantations. Heart retransplantation raises ethical issues due to the lack of sufficient donor hearts for initial transplants. The United Network for Organ Sharing does not have separate organ allocation criteria for repeat heart transplant recipients.

Prioritization of Candidates

Most heart transplant recipients now are hospitalized as status 1 patients 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 recipients. Patients initially listed as status 2 candidates may deteriorate to a status 1 candidate before a donor organ becomes available. Alternatively, as medical and device therapy for advanced heart failure improves, some patients on the transplant list will recover enough function to be delisted. Lietz and Miller (2007) reported on survival for patients on the heart transplant waiting list, comparing the era between 1990 and 1994 with the era of 2000 to 2005. One-year survival for United Network for Organ Sharing status 1 candidates improved from 49.5% to 69.0%. Status 2 candidates fared even better, with 89.4% surviving 1 year compared with 81.8% in the earlier time period.

Johnson et al (2010) reported on waiting list trends in the United States between 1999 and 2008. The proportion of patients listed as status 1 increased, even as waiting list and posttransplant mortality for this group has decreased. Meanwhile, status 2 patients have decreased as a proportion of all candidates. Completed transplants have trended toward the extremes of age, with more infants and patients older than age 65 years having transplants in recent years.

As a consequence, aggressive treatment of heart failure has been emphasized in recent guidelines. Prognostic criteria have been investigated to identify patients who have truly exhausted medical therapy and thus are likely to derive the maximum benefit for heart transplantation. Maximal oxygen consumption ($VO_2\text{max}$), which is measured during maximal exercise, is a measure suggested as a critical objective criterion of the functional reserve of the heart. The American College of Cardiology and American Heart Association have adopted $VO_2\text{max}$ as a criterion for patient selection. Studies have suggested that transplantation can be safely deferred in those patients with a $VO_2\text{max}$ of greater than 14 mL/kg/min. The importance of the $VO_2\text{max}$ has also been emphasized by the American Heart Association when addressing heart transplant candidacy. In past years, a left ventricular ejection fraction of less than 20% or a New York Heart Association class III or IV status might have been used to determine transplant candidacy. However, as indicated by the American College of Cardiology criteria, these measurements are no longer considered adequate to identify transplant candidates. These measurements may be used to identify patients for further cardiovascular workup but should not be the sole criteria for transplant.

Methods other than $VO_2\text{max}$ have been proposed as predictive models in adults. The Heart Failure Survival Scale and the Seattle Heart Failure Model (SHFM) are examples. In particular, the SHFM provides an estimate of 1-, 2-, and 3-year survival with the use of routinely obtained clinical and

laboratory data. Information on pharmacologic and device usage is incorporated into the model, permitting some estimation on effects of current, more aggressive heart failure treatment strategies. Levy et al (2006) introduced the model using a multivariate analysis of data from the Prospective Randomized Amlodipine Survival Evaluation-1 heart failure trial (N=1125). Applied to the data of 5 other heart failure trials, SHFM correlated well with actual survival ($r=0.98$). SHFM has been validated in both ambulatory and hospitalized heart failure populations, but with a noted underestimation of mortality risk, particularly in blacks and device recipients. None of these models has been universally adopted by transplant centers.

Summary

For individuals who have end-stage heart failure who receive a heart transplant, the evidence includes case series and registry data. Relevant outcomes are overall survival, symptoms, morbid events, and treatment-related morbidity and mortality. Despite improvements in the prognosis for many patients with advanced heart disease, heart transplant remains a viable treatment for those with severe heart dysfunction despite appropriate medical management with medication, surgery, or medical devices. Given the exceedingly poor survival rates without transplantation for these patients, evidence of post-transplant survival is sufficient to demonstrate that heart transplantation provides a survival benefit. Heart transplantation is contraindicated in patients for whom the procedure is expected to be futile due to comorbid disease or in whom post transplantation care is expected to worsen comorbid conditions significantly. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have had a prior heart transplant complicated by graft failure or severe dysfunction of the heart who receive a heart retransplant, the evidence includes case series and registry data. Relevant outcomes are overall survival, symptoms, morbid events, and treatment-related morbidity and mortality. Despite improvements in the prognosis for many patients with graft failure, cardiac allograft vasculopathy, and severe dysfunction of the transplanted heart, heart retransplant remains a viable treatment for those who have exhausted other medical or surgical remedies, yet are still with severe symptoms. Given the exceedingly poor survival rates without retransplantation for patients who have exhausted other treatments, evidence of post-transplant survival is sufficient to demonstrate that heart retransplantation provides a survival benefit in appropriately selected patients. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Policy History

Date	Action
10/2018	BCBSA National medical policy review. No changes to policy statements. New references added. Background and summary clarified.
2/2018	Clarified coding information.
11/2017	New references added from BCBSA National medical policy.
1/2016	New references added from BCBSA National medical policy.
11/2015	Added coding language.
12/2014	New references added to BCBSA National medical policy.
10/2014	Medical policy remediation: New indications for non-coverage. Coding information clarified. Effective 10/1/2014.
6/2014	Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.
4/2014	BCBSA National medical policy review. New medically necessary and investigational indications described. Effective 4/1/2014.
12/2013	Removed ICD-9 diagnosis codes as this policy requires prior authorization
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
10/2011	Medical Policy Group - GI, Nutrition and Organ Transplantation. No changes to policy statements.

3/22/2011	Clarified medical necessity criteria based on revision of the BCBSA policy.
11/2010	Medical Policy Group - Gastroenterology, Nutrition and Organ Transplantation. No changes to policy statements.
5/20/2010	Updated to clarify and reword when services are not covered section. No changes to policy statement.
3/2010	National Policy Review # 7.03.09. Revision to policy statement.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

[Medical Policy Terms of Use](#)

[Managed Care Guidelines](#)

[Indemnity/PPO Guidelines](#)

[Clinical Exception Process](#)

[Medical Technology Assessment Guidelines](#)

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