MASSACHUSETTS

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Medical Policy
Heart Transplant

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Policy Number: 197

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NCD/LCD: N/A

Related Policies

- Heart-Lung Transplant, #269
- Total Artificial Hearts and Ventricular Assist Devices, #280
- Immune Cell Function Assay in Solid Organ Transplantation, #182

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue^{SM} and Medicare PPO Blue^{SM} 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 Vo_2 >15 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

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	This procedure is performed in the inpatient setting.
Commercial PPO and Indemnity	This procedure is performed in the inpatient setting.
Medicare HMO Blue℠	This procedure is performed in the inpatient setting.
Medicare PPO Blue℠	This procedure is performed in the inpatient setting.

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

Solid Organ Transplantation

Solid organ transplantation offers a treatment option for patients with different types of end-stage organ failure that can be lifesaving or provide significant improvements to a patient's quality of life.[1,] Many advances have been made in the last several decades to reduce perioperative complications. Available data supports improvement in long-term survival as well as improved quality of life, particularly for liver, kidney, pancreas, heart, and lung transplants. Allograft rejection remains a key early and late complication risk for any organ transplantation. Transplant recipients require life-long immunosuppression to prevent rejection. Patients are prioritized for transplant by mortality risk and severity of illness criteria developed by Organ Procurement and Transplantation Network and United Network for Organ Sharing.

Heart Transplant

In 2019, 39,719 transplants were performed in the United States procured from almost 11,900 deceased donors and 7,400 living donors.[2,] Heart transplants were the third most common procedure with 3,552 transplants performed from both deceased and living donors in 2019. As of June 2020, there were 3,501 patients on the waiting list for a heart transplant.[3,]

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 for 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.[4,] One-year survival for United Network for Organ Sharing status 1 candidate 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 U. S. between 1999 and 2008.[5,] The proportion of patients listed as status 1 increased, even as the waiting list and posttransplant mortality for this group have 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.

Alshawabkeh et al (2018) reported on the 1-year probability of the combined outcome of death or delisting due to clinical worsening for patients on the heart transplant waiting list, comparing the periods of April 1, 1986 to January 19, 1999, (early era) and January 20, 1999 to June 2, 2014 (current era).[6,] For adults without congenital heart disease (CHD), the probability of the combined outcome was lower in the current era compared with the early era, regardless of whether the patient was listed in status I (14.5% vs 22.7%; p<0.0001) or 2 (9.0% vs 12.8%, p<0.0001). When comparing the current and early eras in adults with CHD, a reduction in the probability of the combined outcome was demonstrated in those listed in status I (17.6% vs 43.3%, respectively; p<0.0001), whereas the outcome remained unchanged for those listed in status 2 (10.6% vs 10.4%, respectively; p=0.94).

In adults with CHD, factors associated with waitlist death or delisting due to clinical worsening within 1 year were also examined by Alshawabkeh et al (2016).[7,] A multivariate analysis identified that an estimated glomerular filtration rate less than 60 ml/min/1.73 m^2 (hazard ratio [HR], 1.4; 95% confidence interval [CI], 1.0 to 1.9; p=0.043), albumin less than 3.2 g/dl (HR, 2.0; 95% CI, 1.3 to 2.9; p<0.001), and hospitalization at the time of listing in the intensive care unit (HR, 2.3; 95% CI, 1.6 to 3.5; p<0.001) or a non-intensive care hospital unit (HR, 1.9; 95% CI, 1.2 to 3.0; p=0.006) were associated with waitlist death or delisting due to clinical worsening within 1 year.

Magnetta et al (2019) reported outcomes for children on the heart transplant waiting list, comparing the periods of December 16, 2011 to March 21, 2016 (era 1), and March 22, 2016 to June 30, 2018 (era 2).[8,] There was a significant decrease from era 1 to era 2 in the proportion of patients listed as status 1 (70% vs 56%; p<0.001), while the proportion of patients with CHD significantly increased across eras (49% to 54%; p=0.018). The median time on the waitlist increased from 68 days to 78 days (p=0.005). There were no significant differences across eras in the cumulative incidence of death on the waitlist among all candidates (subdistribution hazard ratio, 0.96; 95% CI, 0.80 to 1.14; p=0.63) and among those listed status 1A (subdistribution hazard ratio, 1.16; 95% CI, 0.95 to 1.41; p= 0.14). Graft survival at 90 days was also similar across eras in the overall population and in those with CHD (p>0.53 for both).

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_2max), 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_2max as a criterion for patient selection.[9] Studies have suggested that transplantation can be safely deferred in those patients with a VO_2max greater than 14 mL/kg/min. The importance of VO_2max has also been emphasized by the American Heart Association when addressing heart transplant candidacy.[10] 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_2max have been proposed as predictive models in adults.[11,12,13,14] 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 the 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).[15] 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,[16,17,18] but with a noted underestimation of mortality risk, particularly in blacks and device recipients.[19,20] None of these models has been universally adopted by transplant centers.

Summary

A heart transplant and a retransplant consists of replacing a diseased heart with a healthy donor heart. Transplantation is used for patients with refractory end-stage cardiac disease.

For individuals who have end-stage heart failure who receive a heart transplant, the evidence includes retrospective studies and registry data. Relevant outcomes are OS, symptoms, and morbid events, 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 for patients for whom the procedure is expected to be futile due to comorbid disease or for whom posttransplantation 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 systematic reviews, retrospective studies, and registry data. Relevant outcomes are OS, symptoms, and morbid events. 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 whose severe symptoms persist despite treatment with other medical or surgical remedies. 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
10/2020	BCBSA National medical policy review. Description, summary, and references updated. Policy statement(s) unchanged.

10/2019	BCBSA National medical policy review. No changes to policy statements. New references added. Background and summary clarified.
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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