MEDICAL POLICY

POLICY TITLE	HEART TRANSPLANT
POLICY NUMBER	MP-9.007

Original Issue Date (Created):	**8/9/2002**
Most Recent Review Date (Revised):	**5/27/2020**
Effective Date:	**8/1/2020**

I. POLICY

Human heart transplantation may be considered **medically necessary** for selected adults and children with end-stage heart failure when patient selection criteria are met.

Adult Patients

I. Accepted Indications for Transplantation

1. Hemodynamic compromise due to heart failure demonstrated by any of the following three (3) bulleted items:
   - Maximal oxygen consumption (Vo_2) less than 10 mL/kg/min with achievement of anaerobic metabolism; **or**
   - Refractory cardiogenic shock; **or**
   - Documented dependence on intravenous inotropic support to maintain adequate organ perfusion; **or**
2. Severe ischemia consistently limiting routine activity not amenable to bypass surgery or angioplasty; **or**
3. Recurrent symptomatic ventricular arrhythmias refractory to all accepted therapeutic modalities.

II. Probable Indications for Cardiac Transplantation

1. Maximal Vo_2 less than 14 mL/kg/min and major limitation of the patient's activities; **or**
2. Recurrent unstable ischemia not amenable to bypass surgery or angioplasty; **or**
3. Instability of fluid balance/renal function not due to patient noncompliance with regimen of weight monitoring, flexible use of diuretic drugs, and salt restriction.

III. The following conditions are inadequate indications for transplantation unless other factors as listed above are present.

1. Ejection fraction less than 20%; **or**
2. History of functional class III or IV symptoms of heart failure; **or**
3. Previous ventricular arrhythmias; **or**
4. Maximal Vo_2 greater than 15 mL/kg/min.

Pediatric Patients

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

1. Continuous infusion of intravenous inotropic agents; **or**
2. Mechanical ventilatory support; **or**
3. Mechanical circulatory support.

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

1. Severe limitation of exercise and activity (if measurable, such patients would have a peak maximum Vo2 less than 50% predicted for age and sex); **or**
2. Cardiomyopathies or previously repaired or palliated congenital heart disease and significant growth failure attributable to the heart disease; **or**
3. Near sudden death and/or life-threatening arrhythmias untreatable with medications or an implantable defibrillator; **or**
4. Restrictive cardiomyopathy with reactive pulmonary hypertension; **or**
5. Reactive pulmonary hypertension and potential risk of developing fixed, irreversible elevation of pulmonary vascular resistance that could preclude orthotopic heart transplantation in the future; **or**
6. Anatomical and physiological conditions likely to worsen the natural history of congenital heart disease in infants with a functional single ventricle; **or**
7. Anatomical and physiological conditions that may lead to consideration for 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 considered **investigational** in all other situations. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

POLICY TITLE	HEART TRANSPLANT
POLICY NUMBER	MP-9.007

POLICY GUIDELINES

General Criteria

Potential contraindications for solid organ transplant are subject to the judgment of the transplant center include the following:

- Known current malignancy, including metastatic cancer; **or**
- Recent malignancy with high risk of recurrence; **or**
- Untreated systemic infection making immunosuppression unsafe, including chronic infection; **or**
- Other irreversible end-stage disease not attributed to heart or lung disease
- History of cancer with a moderate risk of recurrence; **or**
- Systemic disease that could be exacerbated by immunosuppression; **or**
- Psychosocial conditions or chemical dependency affecting ability to adhere to therapy

Policy specific potential contraindications:

- Pulmonary hypertension that is fixed as evidenced by pulmonary vascular resistance (PVR) greater than 5 Wood units, or trans-pulmonary gradient (TPG) greater than or equal to 16 mm/Hg despite treatment*; **or**
- Severe pulmonary disease despite optimal medical therapy, not expected to improve with heart transplantation*.

*Some patients may be candidates for combined heart-lung transplantation (refer to MP-9.014, Heart/Lung Transplant).

Patients must meet the United Network for Organ Sharing (UNOS) guidelines for status 1A, 1B, or s 2 (and not currently be status 7).

Cardiac Specific Criteria

Specific criteria for prioritizing donor thoracic organs for transplant are provided by the Organ Procurement and Transplantation Network (OPTN) and implemented through a contract with UNOS. Donor thoracic organs are prioritized by UNOS on the basis of recipient medical urgency, distance from donor hospital, and pediatric status. Patients who are most severely ill (status 1A) are given highest priority. The following factors are considered in assessing the severity of illness: reliance on continuous mechanical ventilation, infusion of intravenous inotropes, and/or dependency on mechanical circulatory support (i.e., total artificial heart, intra-aortic balloon pump, extracorporeal membrane oxygenator, ventricular assist device).

Additional criteria, which are considered in pediatric patients, include diagnosis of a OPTN-approved congenital heart disease diagnosis, presence of ductal dependent pulmonary or systemic circulation, and diagnosis of hypertrophic or restrictive cardiomyopathy while less than one (1) year old. Of note, pediatric heart transplant candidates who remain on the waiting

list at the time of their 18th birthday without receiving a transplant continue to qualify for medical urgency status based on the pediatric criteria.

Specific criteria for prioritizing donor thoracic organs for retransplant include severe coronary allograft vasculopathy, mild or moderate coronary allograft vasculopathy with a left ventricular ejection fraction less than 45%, coronary allograft vasculopathy with restrictive physiology, or symptomatic graft dysfunction without evidence of active rejection.

Cross-references:

MP-9.014 Heart/Lung Transplant
MP-1.026 Total Artificial Hearts and Implantable Ventricular Assist Devices

II. PRODUCT VARIATIONS

TOP

This policy is applicable to all programs and products administered by Capital BlueCross unless otherwise indicated below.

FEP PPO: Refer to FEP Medical Policy Manual MP-7.03.08, Heart and Lung Transplant. The FEP Medical Policy Manual can be found at https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies.

III. DESCRIPTION/BACKGROUND

TOP

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 transplantation can potentially improve both survival and quality of life in patients with end-stage heart failure.

Heart failure may be due to a number of differing etiologies, including ischemic heart disease, cardiomyopathy, or congenital heart defects. The leading indication for 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.[2] 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.

POLICY TITLE	HEART TRANSPLANT
POLICY NUMBER	MP-9.007

Treatment

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 2016, a total of 3191 heart transplants were performed in the United States.[3] As of July 16, 2017, there were 3996 patients on the waiting list for a heart transplant. In recent years, innovations in medical and device therapy for patients with advanced heart failure has also improved the survival of patients awaiting heart transplantation. 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.[4]

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 one (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 two (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 one (1) candidates improved from 49.5% to 69.0%. Status two (2) candidates fared even better, with 89.4% surviving one (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 two (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_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. Studies have suggested that transplantation can be safely deferred in those patients with a VO_2max of greater than 14 mL/kg/min. The importance of the VO_2max 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_2max 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 five (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.

Regulatory Status

Heart transplantation is a surgical procedure and, as such, is not subject to regulation by the U.S. Food and Drug Administration.

The U.S. Food and Drug Administration regulates human cells and tissues intended for implantation, transplantation, or infusion through the Center for Biologics Evaluation and Research, under Code of Federal Regulation title 21, parts 1270 and 1271. Heart transplants are included in these regulations.

IV. RATIONALE

TOP

Summary of Evidence

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 posttransplant 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 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 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 posttransplant 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.

V. DEFINITIONS

TOP

ARRHYTHMIA refers to irregularity or loss of rhythm, especially of the heart.

CARDIOMYOPATHY is any disease that affects the heart muscle, diminishing cardiac performance.

EJECTION FRACTION refers to in cardiac physiology, the percentage of the blood emptied from the ventricle during systole.

NEW YORK HEART ASSOCIATION CLASS III refers to patients with cardiac disease, which results in marked limitation of physical activity. These patients are comfortable at rest. Less than ordinary activity causes fatigue, palpitation, dyspnea, or anginal pain.

NEW YORK HEART ASSOCIATION CLASS IV refers to patients with cardiac disease, which results in the inability to carry out any physical activity without discomfort. Symptoms of heart failure or the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increased.

United Network for Organ Sharing (UNOS) is an organization established in 1984 to facilitate donation of organs for possible transplantation.

VI. BENEFIT VARIATIONS

TOP

The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and

providers should consult the member's benefit information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

TOP

Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

TOP

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary:

CPT Codes ®							
33940	33944	33945					

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 posttransplant care in the global definition

ICD-10-CM Diagnosis Codes	Description
I25.110	Atherosclerotic heart disease of native coronary artery with unstable angina pectoris
I25.111	Atherosclerotic heart disease of native coronary artery with angina pectoris with documented spasm
I25.118	Atherosclerotic heart disease of native coronary artery with other forms of angina pectoris
I25.119	Atherosclerotic heart disease of native coronary artery with unspecified angina pectoris
I25.5	Ischemic cardiomyopathy

POLICY TITLE	HEART TRANSPLANT
POLICY NUMBER	MP-9.007

ICD-10-CM Diagnosis Codes	Description
I25.6	Silent myocardial ischemia
I25.700	Atherosclerosis of coronary artery bypass graft(s), unspecified, with unstable angina pectoris
I25.701	Atherosclerosis of coronary artery bypass graft(s), unspecified, with angina pectoris with documented spasm
I25.708	Atherosclerosis of coronary artery bypass graft(s), unspecified, with other forms of angina pectoris
I25.709	Atherosclerosis of coronary artery bypass graft(s), unspecified, with unspecified angina pectoris
I25.710	Atherosclerosis of autologous vein coronary artery bypass graft(s) with unstable angina pectoris
I25.711	Atherosclerosis of autologous vein coronary artery bypass graft(s) with angina pectoris with documented spasm
I25.718	Atherosclerosis of autologous vein coronary artery bypass graft(s) with other forms of angina pectoris
I25.719	Atherosclerosis of autologous vein coronary artery bypass graft(s) with unspecified angina pectoris
I25.720	Atherosclerosis of autologous artery coronary artery bypass graft(s) with unstable angina pectoris
I25.721	Atherosclerosis of autologous artery coronary artery bypass graft(s) with angina pectoris with documented spasm
I25.728	Atherosclerosis of autologous artery coronary artery bypass graft(s) with other forms of angina pectoris
I25.729	Atherosclerosis of autologous artery coronary artery bypass graft(s) with unspecified angina pectoris
I25.730	Atherosclerosis of nonautologous biological coronary artery bypass graft(s) with unstable angina pectoris
I25.731	Atherosclerosis of nonautologous biological coronary artery bypass graft(s) with angina pectoris with documented spasm
I25.738	Atherosclerosis of nonautologous biological coronary artery bypass graft(s) with other forms of angina pectoris
I25.739	Atherosclerosis of nonautologous biological coronary artery bypass graft(s) with unspecified angina pectoris
I25.750	Atherosclerosis of native coronary artery of transplanted heart with unstable angina
I25.751	Atherosclerosis of native coronary artery of transplanted heart with angina pectoris with documented spasm
I25.758	Atherosclerosis of native coronary artery of transplanted heart with other forms of angina pectoris
I25.759	Atherosclerosis of native coronary artery of transplanted heart with unspecified angina pectoris
I25.760	Atherosclerosis of bypass graft of coronary artery of transplanted heart with unstable angina

POLICY TITLE	HEART TRANSPLANT
POLICY NUMBER	MP-9.007

ICD-10-CM Diagnosis Codes	Description
I25.761	Atherosclerosis of bypass graft of coronary artery of transplanted heart with angina pectoris with documented spasm
I25.768	Atherosclerosis of bypass graft of coronary artery of transplanted heart with other forms of angina pectoris
I25.769	Atherosclerosis of bypass graft of coronary artery of transplanted heart with unspecified angina pectoris
I25.790	Atherosclerosis of other coronary artery bypass graft(s) with unstable angina pectoris
I25.791	Atherosclerosis of other coronary artery bypass graft(s) with angina pectoris with documented spasm
I25.798	Atherosclerosis of other coronary artery bypass graft(s) with other forms of angina pectoris
I25.799	Atherosclerosis of other coronary artery bypass graft(s) with unspecified angina pectoris
I25.810	Atherosclerosis of coronary artery bypass graft(s) without angina pectoris
I25.811	Atherosclerosis of native coronary artery of transplanted heart without angina pectoris
I25.812	Atherosclerosis of bypass graft of coronary artery of transplanted heart without angina pectoris
I25.82	Chronic total occlusion of coronary artery
I25.83	Coronary atherosclerosis due to lipid rich plaque
I25.84	Coronary atherosclerosis due to calcified coronary lesion
I25.89	Other forms of chronic ischemic heart disease
I25.9	Chronic ischemic heart disease, unspecified
I47.0	Re-entry ventricular arrhythmia
I47.1	Supraventricular tachycardia
I47.2	Ventricular tachycardia
I47.9	Paroxysmal tachycardia, unspecified
I49.01	Ventricular fibrillation
I49.02	Ventricular flutter
I50.1	Left ventricular failure
I50.20	Unspecified systolic (congestive) heart failure
I50.21	Acute systolic (congestive) heart failure
I50.22	Chronic systolic (congestive) heart failure
I50.23	Acute on chronic systolic (congestive) heart failure
I50.30	Unspecified diastolic (congestive) heart failure
I50.31	Acute diastolic (congestive) heart failure
I50.32	Chronic diastolic (congestive) heart failure
I50.33	Acute on chronic diastolic (congestive) heart failure
I50.40	Unspecified combined systolic (congestive) and diastolic (congestive) heart failure
I50.41	Acute combined systolic (congestive) and diastolic (congestive) heart failure
I50.42	Chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.43	Acute on chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.811	Acute right heart failure
I50.812	Chronic right heart failure

POLICY TITLE	HEART TRANSPLANT
POLICY NUMBER	MP-9.007

ICD-10-CM Diagnosis Codes	Description
I50.813	Acute on chronic right heart failure
I50.814	Right heart failure due to left heart failure
I50.82	Biventricular heart failure
I50.83	High output heart failure
I50.84	End stage heart failure
I50.89	Other heart failure
I50.9	Heart failure, unspecified
R09.02	Hypoxemia
R57.0	Cardiogenic shock
T86.22	Heart Transplant Failure

IX. REFERENCES

TOP

1. *Benjamin EJ, Blaha MJ, Chiuve SE, et al. Heart Disease and Stroke Statistics-2017 Update: A Report From the American Heart Association. Circulation. Mar 07 2017;135(10):e146-e603. PMID 28122885*
2. *Lund LH, Edwards LB, Dipchand AI, et al. The Registry of the International Society for Heart and Lung Transplantation: Thirty-third Adult Heart Transplantation Report-2016; Focus Theme: Primary Diagnostic Indications for Transplant. J Heart Lung Transplant. Oct 2016;35(10):1158-1169. PMID 27772668*
3. *Organ Procurement and Transplantation Network (OPTN). National data. 2018; https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/. Accessed May 27,2020.*
4. *Organ Procurement and Transplantation Network (OPTN). Organ Procurement and Transplantation Network Policies. 2018; https://optn.transplant.hrsa.gov/governance/policies/. Accessed May 27, 2020.*
5. *Lietz K, Miller LW. Improved survival of patients with end-stage heart failure listed for heart transplantation: analysis of organ procurement and transplantation network/U.S. United Network of Organ Sharing data, 1990 to 2005. J Am Coll Cardiol. Sep 25 2007;50(13):1282-1290. PMID 17888847*
6. *Johnson MR, Meyer KH, Haft J, et al. Heart transplantation in the United States, 1999-2008. Am J Transplant. Apr 2010;10(4 Pt 2):1035-1046. PMID 20420651*
7. *Hunt SA, Abraham WT, Chin MH, et al. ACC/AHA 2005 Guideline Update for the Diagnosis and Management of Chronic Heart Failure in the Adult: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Update the 2001 Guidelines for the Evaluation and Management of Heart Failure): developed in collaboration with the American College of Chest Physicians and the*

International Society for Heart and Lung Transplantation: endorsed by the Heart Rhythm Society. Circulation. Sep 20 2005;112(12):e154-e235. PMID 16160202

8. *Costanzo MR, Augustine S, Bourge R, et al. Selection and treatment of candidates for heart transplantation. A statement for health professionals from the Committee on Heart Failure and Cardiac Transplantation of the Council on Clinical Cardiology, American Heart Association. Circulation. Dec 15 1995;92(12):3593-3612. PMID 8521589*
9. *Aaronson KD, Schwartz JS, Chen TM, et al. Development and prospective validation of a clinical index to predict survival in ambulatory patients referred for cardiac transplant evaluation. Circulation. Jun 17 1997;95(12):2660-2667. PMID 9193435*
10. *Alla F, Briancon S, Juilliere Y, et al. Differential clinical prognostic classifications in dilated and ischemic advanced heart failure: the EPICAL study. Am Heart J. May 2000;139(5):895-904. PMID 10783225*
11. *Hansen A, Haass M, Zugck C, et al. Prognostic value of Doppler echocardiographic mitral inflow patterns: implications for risk stratification in patients with chronic congestive heart failure. J Am Coll Cardiol. Mar 15 2001;37(4):1049-1055. PMID 11263607*
12. *Lee DS, Austin PC, Rouleau JL, et al. Predicting mortality among patients hospitalized for heart failure: derivation and validation of a clinical model. JAMA. Nov 19 2003;290(19):2581-2587. PMID 14625335*
13. *Levy WC, Mozaffarian D, Linker DT, et al. The Seattle Heart Failure Model: prediction of survival in heart failure. Circulation. Mar 21 2006;113(11):1424-1433. PMID 16534009*
14. *Gorodeski EZ, Chu EC, Chow CH, et al. Application of the Seattle Heart Failure Model in ambulatory patients presented to an advanced heart failure therapeutics committee. Circ Heart Fail. Nov 2010;3(6):706-714. PMID 20798278*
15. *Ketchum ES, Moorman AJ, Fishbein DP, et al. Predictive value of the Seattle Heart Failure Model in patients undergoing left ventricular assist device placement. J Heart Lung Transplant. Sep 2010;29(9):1021-1025. PMID 20558086*
16. *Nutter AL, Tanawuttiwat T, Silver MA. Evaluation of 6 prognostic models used to calculate mortality rates in elderly heart failure patients with a fatal heart failure admission. Congest Heart Fail. Sep-Oct 2010;16(5):196-201. PMID 20887615*
17. *Kalogeropoulos AP, Georgiopoulou VV, Giamouzis G, et al. Utility of the Seattle Heart Failure Model in patients with advanced heart failure. J Am Coll Cardiol. Jan 27 2009;53(4):334-342. PMID 19161882*
18. *May HT, Horne BD, Levy WC, et al. Validation of the Seattle Heart Failure Model in a community-based heart failure population and enhancement by adding B-type natriuretic peptide. Am J Cardiol. Aug 15 2007;100(4):697-700. PMID 17697831*
19. *Nguyen VP, Mahr C, Mokadam NA, et al. The benefit of donor-recipient matching for patients undergoing heart transplantation. J Am Coll Cardiol. Apr 04 2017;69(13):1707-1714. PMID 28359517*
20. *Rana A, Gruessner A, Agopian VG, et al. Survival benefit of solid-organ transplant in the United States. JAMA Surg. Mar 1 2015;150(3):252-259. PMID 25629390*

21. *Jaramillo N, Segovia J, Gomez-Bueno M, et al. Characteristics of patients with survival longer than 20 years following heart transplantation. Rev Esp Cardiol. Oct 2013;66(10):797-802. PMID 23932221*
22. *Kilic A, Weiss ES, George TJ, et al. What predicts long-term survival after heart transplantation? An analysis of 9,400 ten-year survivors. Ann Thorac Surg. Mar 2012;93(3):699-704. PMID 22226494*
23. *Dipchand AI, Kirk R, Mahle WT, et al. Ten yr of pediatric heart transplantation: a report from the Pediatric Heart Transplant Study. Pediatr Transplant. Mar 2013;17(2):99-111. PMID 23442098*
24. *Auerbach SR, Richmond ME, Chen JM, et al. Multiple risk factors before pediatric cardiac transplantation are associated with increased graft loss. Pediatr Cardiol. Jan 2012;33(1):49-54. PMID 21892650*
25. *Rossano JW, Dipchand AI, Edwards LB, et al. The Registry of the International Society for Heart and Lung Transplantation: Nineteenth Pediatric Heart Transplantation Report-2016; Focus Theme: Primary Diagnostic Indications for Transplant. J Heart Lung Transplant. Oct 2016;35(10):1185-1195. PMID 27772670*
26. *Savla J, Lin KY, Lefkowitz DS, et al. Adolescent age and heart transplantation outcomes in myocarditis or congenital heart disease. J Heart Lung Transplant. Sep 2014;33(9):943-949. PMID 24929645*
27. *Almond CSD, Thiagarajan RR, Piercey GE, et al. Waiting list mortality among children listed for heart transplantation in the United States. Circulation. Feb 10 2009;119(5):717-727. PMID 19171850*
28. *Tjang YS, Tenderich G, Hornik L, et al. Cardiac retransplantation in adults: an evidence-based systematic review. Thorac Cardiovasc Surg. Sep 2008;56(6):323-327. PMID 18704853*
29. *Saito A, Novick RJ, Kiaii B, et al. Early and late outcomes after cardiac retransplantation. Can J Surg. Feb 2013;56(1):21-26. PMID 23187039*
30. *Goldraich LA, Stehlik J, Kucheryavaya AY, et al. Retransplant and medical therapy for cardiac allograft vasculopathy: international society for heart and lung transplantation registry analysis. Am J Transplant. Jan 2016;16(1):301-309. PMID 26274617*
31. *Belli E, Leoni Moreno JC, Hosenpud J, et al. Preoperative risk factors predict survival following cardiac retransplantation: analysis of the United Network for Organ Sharing database. J Thorac Cardiovasc Surg. Jun 2014;147(6):1972-1977, 1977 e1971. PMID 24636155*
32. *Friedland-Little JM, Gajarski RJ, Yu S, et al. Outcomes of third heart transplants in pediatric and young adult patients: analysis of the United Network for Organ Sharing database. J Heart Lung Transplant. Sep 2014;33(9):917-923. PMID 24861821*
33. *Bock MJ, Nguyen K, Malerba S, et al. Pediatric cardiac retransplantation: Waitlist mortality stratified by age and era. J Heart Lung Transplant. Apr 2015;34(4):530-537. PMID 25016920*

34. *Conway J, Manlhiot C, Kirk R, et al. Mortality and morbidity after retransplantation after primary heart transplant in childhood: an analysis from the registry of the International Society for Heart and Lung Transplantation. J Heart Lung Transplant. Mar 2014;33(3):241-251. PMID 24462559*
35. *Mistiaen WP. Heart transplantation in patients with previous malignancy. An overview. Acta Cardiol. Apr 2015;70(2):123-130. PMID 26148371*
36. *Oliveira GH, Hardaway BW, Kucheryavaya AY, et al. Characteristics and survival of patients with chemotherapy-induced cardiomyopathy undergoing heart transplantation. J Heart Lung Transplant. Aug 2012;31(8):805-810. PMID 22551930*
37. *Sigurdardottir V, Bjortuft O, Eiskjaer H, et al. Long-term follow-up of lung and heart transplant recipients with pre-transplant malignancies. J Heart Lung Transplant. Dec 2012;31(12):1276-1280. PMID 23089300*
38. *Yoosabai A, Mehta A, Kang W, et al. Pretransplant malignancy as a risk factor for posttransplant malignancy after heart transplantation. Transplantation. Feb 2015;99(2):345-350. PMID 25606783*
39. *Aguero F, Castel MA, Cocchi S, et al. An update on heart transplantation in human immunodeficiency virus-infected patients. Am J Transplant. Jan 2016;16(1):21-28. PMID 26523614*
40. *Uriel N, Jorde UP, Cotarlan V, et al. Heart transplantation in human immunodeficiency virus-positive patients. J Heart Lung Transplant. Jul 2009;28(7):667-669. PMID 19560693*
41. *Working Party of the British Transplantation Society. Kidney and Pancreas Transplantation in Patients with HIV. Second Edition (Revised). British Transplantation Society Guidelines. Macclesfield, UK: British Transplantation Society; 2017.*
42. *Jamil A, Qin H, Felius J, et al. Comparison of Clinical Characteristics, Complications, and Outcomes in Recipients Having Heart Transplants <65 Years of Age Versus ≥65 Years of Age. Am J Cardiol. Sep 15 2017 120(12):2207-2212. PMID 29056228*
43. *Cooper LB, Lu D, Mentz RJ, et al. Cardiac transplantation for older patients: Characteristics and outcomes in the septuagenarian population. J Heart Lung Transplant. Mar 2016;35(3):362-369. PMID 26632028*
44. *Awad M, Czer LS, Mirocha J, et al. Similar mortality and morbidity of orthotopic heart transplantation for patients 70 years of age and older compared with younger patients. Transplant Proc. Oct 2016;48(8):2782-2791. PMID 27788818*
45. *Kilic A, Weiss ES, Yuh DD, et al. Factors associated with 5-year survival in older heart transplant recipients. J Thorac Cardiovasc Surg. Feb 2012;143(2):468-474. PMID 22248684*
46. *De Santo LS, Romano G, Maiello C, et al. Pulmonary artery hypertension in heart transplant recipients: how much is too much? Eur J Cardiothorac Surg. Nov 2012;42(5):864-869; discussion 869-870. PMID 22402452*

47. *Perez-Villa F, Farrero M, Cardona M, et al. Bosentan in heart transplantation candidates with severe pulmonary hypertension: efficacy, safety and outcome after transplantation. Clin Transplant. Jan-Feb 2013;27(1):25-31. PMID 22861120*
48. *Pons J, Leblanc MH, Bernier M, et al. Effects of chronic sildenafil use on pulmonary hemodynamics and clinical outcomes in heart transplantation. J Heart Lung Transplant. Dec 2012;31(12):1281-1287. PMID 23127754*
49. *Bedanova H, Orban M, Vrsansky D, et al. Impact of pulmonary hypertension on early hemodynamics, morbidity and mortality after orthotopic heart transplantation. A single center study. Biomed Pap Med Fac Univ Palacky Olomouc Czech Repub. Mar 2013;157(1):35-40. PMID 23073529*
50. *Tsukashita M, Takayama H, Takeda K, et al. Effect of pulmonary vascular resistance before left ventricular assist device implantation on short- and long-term post-transplant survival. J Thorac Cardiovasc Surg. Nov 2015;150(5):1352-1360, 1361 e1351-1352. PMID 26253875*
51. *Kolsrud O, Karason K, Holmberg E, et al. Renal function and outcome after heart transplantation. J Thorac Cardiovasc Surg. Dec 14 2018 155(4):1593-1604.e1591. PMID 29338859*
52. *Hong KN, Merlo A, Chauhan D, et al. Evidence supports severe renal insufficiency as a relative contraindication to heart transplantation. J Heart Lung Transplant. Jul 2016;35(7):893-900. PMID 27105687*
53. *Goel AN, Iyengar A, Schowengerdt K, et al. Heart transplantation in children with intellectual disability: An analysis of the UNOS database. Pediatr Transplant. Mar 2017;21(2). PMID 27933693*
54. *Wightman A, Bartlett HL, Zhao Q, et al. Prevalence and outcomes of heart transplantation in children with intellectual disability. Pediatr Transplant. Mar 2017;21(2). PMID 27801533*
55. *Prendergast C, McKane M, Dodd DA, et al. The impact of cognitive delay on pediatric heart transplant outcomes. Pediatr Transplant. Mar 2017;21(2). PMID 28191755*
56. *Yancy CW, Jessup M, Bozkurt B, et al. 2017 ACC/AHA/HFSA Focused Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Failure Society of America. Circulation. Apr 28 2017 136(6):e137-e161. PMID 28455343*
57. *Rosenthal D, Chrisant MR, Edens E, et al. International Society for Heart and Lung Transplantation: Practice guidelines for management of heart failure in children. J Heart Lung Transplant. Dec 2004;23(12):1313-1333. PMID 15607659*
58. *Mehra MR, Canter CE, Hannan MM, et al. The 2016 International Society for Heart Lung Transplantation listing criteria for heart transplantation: A 10-year update. J Heart Lung Transplant. Jan 2016;35(1):1-23. PMID 26776864*
59. *Costanzo MR, Dipchand A, Starling R, et al. The International Society of Heart and Lung Transplantation Guidelines for the care of heart transplant recipients. J Heart Lung Transplant. Aug 2010;29(8):914-956. PMID 20643330*

60. *Canter CE, Shaddy RE, Bernstein D, et al. Indications for heart transplantation in pediatric heart disease: a scientific statement from the 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. Circulation. Feb 6 2007;115(5):658-676. PMID 17261651*

61. *Ponikowski P, Voors AA, Anker SD, et al. 2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure: The Task Force for the diagnosis and treatment of acute and chronic heart failure of the European Society of Cardiology (ESC)Developed with the special contribution of the Heart Failure Association (HFA) of the ESC. Eur Heart J. Jul 14 2016;37(27):2129-2200. PMID 27206819*

62. *Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) for HEART TRANSPLANTs (260.9). 2008; https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=112&ncdver=3&CoverageSelection=National&KeyWord=heart+transplant&KeyWordLookUp=Title&KeyWordSearchType=And&clickon=search&bc=gAAAABAAAAAA&. Accessed May 27, 2020.*

63. *Blue Cross Blue Shield Association Medical Policy Reference Manual. 7.03.09, Heart Transplant. June 2019.*

X. POLICY HISTORY

TOP

MP 9.007	**CAC 6/24/03**
	CAC 4/26/05
	CAC 2/28/06 (Title changed from Heartsbreath Test)
	CAC 2/27/07
	CAC 1/29/08 Consensus review
	CAC 11/25/08
	CAC 7/28/09
	CAC 11/30/10 Consensus review
	CAC 4/26/11 Minor review. Policy retitled Heart Transplant. Criteria for laboratory tests for heart transplant rejection removed. Adopted BCBSA criteria for heart transplants which lists selection criteria for both pediatric and adult patients.
	CAC 6/26/12 Consensus review. References updated. FEP variation added. Contraindications moved to policy guidelines. Absolute and relative contraindications combined.
	8/23/12 Admin update. Correction to cross-reference.
	3/07/2013 Admin update. Codes Reviewed

POLICY TITLE	HEART TRANSPLANT
POLICY NUMBER	MP-9.007

	CAC 9/24/13 Consensus review. References updated but no changes to the policy statements. Rationale added.
	CAC 7/22/14 Consensus review. Policy updated. No policy stance changes.
	CAC 7/21/15 Consensus review. No change to policy statements. References and rationale updated. Coding reviewed; ICD-9 codes unranged.
	CAC 7/26/2016 Consensus review. No change to policy statements. References and rationale updated. Codes reviewed.
	Admin update 1/1/17: Product variation section reformatted.
	CAC 7/25/17 Consensus review. No change to policy statements. Added Medicare variation to reference NCD 20.9. References and rationale reviewed. Codes reviewed. S2152 added to policy as a covered service for commercial (not valid for Medicare).
	10/1/17 Admin update. Added new ICD 10 codes effective from 10/1/17.
	1/1/18 Admin update: Medicare variations removed from Commercial Policies.
	4/17/18 Minor revision. Policy Guidelines updated. Description/Background, Rationale and Reference sections updated. Coding Reviewed.
	3/11/19 Consensus review. No change to policy statements. Background, rationale summary and references updated.
	05/27/2020 Consensus review. No change to policy statements. Background, rationale summary and references reviewed.

Top