Clinical Policy: Heart Transplant

Reference Number: IL.CP.MP.520 Coding Implications
Last Review Date: 12/21 Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

New York Heart Association Class III	III: Marked limitation of physical activity. Comfortable at rest. Less than ordinary physical activity causes fatigue, palpitation, dyspnea, or angina pain.
New York Heart Association Class IV CHF	IV: Inability to carry on any physical activity without discomfort. Symptoms of cardiac insufficiency or of the angina syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increased.

Cardiac transplantation remains the treatment of choice for patients with end-stage heart failure with severely impaired functional capacity despite optimal medical therapy. Meridian considers heart transplantation medically necessary for any of the following conditions when the selection criteria listed below are met and none of the contraindications are present.

Policy/Criteria

I. It is the policy of MeridianHealth affiliated with Centene Corporation® heart transplantation is **medically necessary** for the following indications:
   A. Prior authizoration is required for heart transplantation for all member, donors, and potential donor services.
   B. Member must meet the MeridianHealth Policy I.07 – Member Compliance in addition to member completing and signing the member agreement form.
   C. **Indications for *Adult* Heart Transplantation** NYHA class III or IV Heart Failure refractory to optimal medical therapy as evidenced by:
      i. Severe coronary artery disease with refractory angina despite optimized medical therapy that is not amenable to bypass surgery or percutaneous intervention. Patients with refractory angina have ischemia confirmed by testing (ETT, stress ECHO) and symptoms so severe they experience discomfort with ordinary physical activity or have limited physical activity.
      ii. Malignant ventricular arrhythmias refractory to all other accepted therapeutic modalities (medical therapy, Implantable Cardioverter Defibrillator, and/or catheter ablative therapy).
      iii. Refractory heart failure requiring continuous intravenous inotrope.
      iv. Mechanical circulatory support with a left ventricular assist device (LVAD)—(Please refer to Policy F.6 Ventricular Assist Device criteria for bridge to transplant).
      v. Primary cardiac tumors confined to the myocardium, with a low likelihood of metastasis at time of transplantation
      vi. Severe hypertrophic or restrictive cardiomyopathy, with NYHA Class IV symptoms Congenital Heart Disease that is not amenable to surgical

therapy or that has failed previous surgical correction[1]. Patients with complex intracardiac abnormalities and significant pulmonary vascular obstructive disease may require heart/lung transplantation (see heart-lung transplant below).

vii. Adults with congenital heart disease associated with NYHA Class IV heart failure not amenable to palliative or corrective surgery; severe symptomatic cyanotic heart disease not amenable to palliation; post-Fontan procedure with refractory heart failure, persistent protein-losing enteropathy and/or plastic bronchitis despite optimal medical and surgical therapy; pulmonary hypertension with the potential risk of developing fixed, irreversible elevation of PVR that could preclude heart transplantation in the future. In adults with congenital heart failure heart transplantation should not be performed without first considered or attempting surgical repair.

D. **Indications for *Pediatric* heart transplantation in the following clinical situations:**

i. Patients with heart failure with persistent symptoms at rest who require one or more of the following:
   a. Continuous infusion of intravenous inotropic agents, or
   b. Mechanical ventilatory support, or
   c. Mechanical circulatory support.

ii. Patients with pediatric heart disease with symptoms of heart failure who do not meet the above criteria but who have:
   a. Severe limitation of exercise and activity (if measurable, such patients would have a peak maximum oxygen consumption <50% predicted for age and sex), ***or***
   b. Cardiomyopathies or previously repaired or palliated congenital heart disease and significant growth failure attributable to the heart disease, ***or***
   c. Near sudden death and/or life-threatening arrhythmias untreatable with medications or an implantable defibrillator, ***or***
   d. Restrictive cardiomyopathy with reactive pulmonary hypertension, ***or***
   e. 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***
   f. Anatomical and physiological conditions likely to worsen the natural history of congenital heart disease in infants with a functional single ventricle, ***or***
   g. Anatomical and physiological conditions that may lead to consideration for heart transplantation without systemic ventricular dysfunction.

[1] Patel ND. Heart transplantation for adults with congenital heart disease: analysis of the United network for organ sharing database. Ann Thorac Surg-01-SEP-2009;88(3):814-21 Yamani MH and Taylor DO. Heart Transplantation. Cleveland Clinic: Current Clinical Medicine, 2nd ed.

E. **Heart-Lung Transplantation:**
   i. Should be reserved for patients who cannot be treated by heart or lung transplantation alone. Candidates include patients with severe, irreversible disease of the lung parenchyma or vasculature who also have severely compromised left or right ventricular function or other cardiac diseases that would preclude a successful outcome with lung transplantation alone. Examples include Eisenmenger syndrome with congenital heart disease or primary pulmonary hypertension with severe right ventricular failure.

F. **Heart-Liver Transplantation:**
   i. Indications for combined heart-liver transplants include: familial transthyretin amyloidosis, hepatitis C-associated cirrhosis, hemochromatosis, and cardiac cirrhosis.

G. **Repeat Transplant (Heart Retransplantation):**
   i. May be considered MEDICALLY NECESSARY due to primary graft failure, rejection refractory to immunosuppressive therapy and graft coronary artery disease with severe ischemia of the heart graft. *Note:* Retransplantation appears most appropriate for those patients more than 6 months following original heart transplantation, who have severe cardiac allograft vasculopathy and associated left ventricular dysfunction, or allograft dysfunction and progressive symptoms of heart failure in the absence of acute rejection.

H. **Absolute Contraindications:**
   i. Fixed pulmonary HTN (unresponsive to pulmonary vasodilator therapy) as evidenced by:
      a. When the pulmonary vascular resistance (PVR) is >6 Wood units (>400 dynes.sec.cm^{-5}), in adults or children ***or***
      b. The Transpulmonary Gradient (mean pulmonary artery pressure minus mean pulmonary capillary wedge pressure) exceeds 16-20 mmHg. ***or***
      c. Pulmonary artery systolic pressure > 60 mmHg in the presence of a or b
   ii. Recent (within 3 months) peptic ulcer disease or a gastrointestinal bleed not immediately responsive to therapy or intervention.
   iii. Presence of life threatening neuromuscular disorders.
   iv. Pulmonary infarction within the past 8 weeks or recent cerebral infarction due to the increased risk for hemorrhagic conversion during bypass and anticoagulation.
   v. Evidence of irreversible end organ damage due to diabetes (e.g. Retinopathy, nephropathy (unless cardiac-renal transplantation is intended), or significant neuropathy) and/or poorly controlled diabetes mellitus as evidenced by recurrent diabetic ketoacidosis, Nonketotic hyperglycemia, or persistently elevated HgA1C. Type 1 diabetics are often poor transplant candidates but will be evaluated on a case by case basis for candidacy.

vi. Symptomatic severe peripheral vascular (rest pain, ulceration, aortic aneurysm) or carotid artery disease. Surgical or percutaneous intervention may permit transplant consideration on a case by case basis.
vii. Active, clinically significant infection.
    a. HIV infection; Hepatitis C and B patients will be evaluated on a case by case basis. Serum PCR is required. [2]Absence of HIV infection is defined by **all** of the following:
        a. CD4 count greater than 200 cells/mm3 for more than 6 months; ***and***
        b. HIV-1 RNA (viral load) undetectable; ***and***
        c. On stable anti-viral therapy for more than 3 months; ***and***
        d. No other complications from AIDS, such as opportunistic infection (e.g., aspergillus, coccidiomycosis, resistant fungal infections, tuberculosis), Kaposi's sarcoma or other neoplasm
viii. Presence of active or recurrent pancreatitis
ix. Significant chronic functional impairment of other vital organs deemed non reversible in nature:
    a. Renal: creatinine >2.5 mg/dl or creatinine clearance <40 ml/min (whichever is worse); proteinuria >1000mg; significant renal nephropathies (i.e.. glomerulosclerosis, glomeruloscleritis). May be a suitable candidate for heart transplant if inotropic support and hemodynamic management produce a creatinine of 2 mg/dl and creatinine clearance of 50 ml/min. Transplantation may also be advisable as combined heart-kidney transplantation.
    b. Hepatic: bilirubin >2.5 mg/dl without rectifiable, identifiable cause (excludes Gilbert's) such as valve hemolysis or hepatic congestion; ALT or AST >2X normal unless known to be secondary to hepatic ischemic and deemed reversible; INR >1.4 sec in absence of anticoagulation therapy after vitamin K therapy; liver biopsy should be undertaken when clinically indicated. A biopsy demonstrating cirrhosis is an absolute contraindication to transplant, unless it is a heart-liver transplant.
    c. Pulmonary: chronic obstructive disease worse than ATS grade moderate (FEV1 <50% predicted, FEV1 < 1 liter), restrictive lung disease with the diffusing capacity (DLCO/VA) <60%, oxygen dependence, recurrent pulmonary emboli not attributed to reversible causes, any pulmonary malady that may impact long-term survival.
    d. Hematologic: significant irreversible coagulation abnormalities or bleeding diatheses.
x. Excessive obesity (e.g. BMI > 35) or Cachexia (BMI<18).
xi. Active mental illness or psychosocial instability
    a. Psychosocial assessment should be performed before listing for transplantation. Evaluation should include an assessment of the patient's ability to give informed consent and comply with

[2] (Ward, Slutsker, Buehler, Jaffe, Berkelman, & Curran, 1992)

instruction including drug therapy, as well as assessment of the support systems in place at home or in the community;

b. Severe cognitive impairement, as it pertains to the ability to follow post-transplant instructions may be regarded as a relative contraindication to transplantation;

c. Poor compliance with drug regimens is a risk factor for graft rejection and mortality. Patients who have demonstrated an inability to comply with drug therapy on multiple occasions should not receive transplantation.

xii. Active or recent malignancy (to be evaluated on a case by case base. Some low risk malignancies, such as superficial skin cancers, may not be contraindicated) Amyloidosis (exceptions may be made in circumstances where curative therapy of amyloidosis has been performed or is planned (e.g., stem cell transplantation in primary amyloidosis, liver transplantation in familial amyloidosis).

xiii. Age > 70

xiv. Other comorbidities known to increase the risk of post-transplant mortality will be evaluated on a case by case basis, including and not limited to: malnutrition, severe deconditioning, advanced age, memory impairment, severe collagen vascular disease, or any other major chronic or disabling illness that may impact rehabilitation or potential for long-term survival.

I. **Member Assessment of Compliance with Plan of Care (applicable for ages 10 and above).** Transplant will not be approved if any one of the following indicators of non-compliance are observed or documented:

i. Alcohol screen- abstinence for the past 6 months prior to actual transplant approval, if member history includes use of alcohol. If no history exists then 1 negative alcohol screen must be submitted for members with no history of past alcohol use

ii. Drug screen-abstinence for the past 6 months prior to actual transplant approval if history exists of drug use. If no history exists then 1 negative drug screen must be submitted for members with no history of positive drug screen.

iii. Nicotine screening- abstinence for the past 6 months prior to actual transplant approval if history of smoking. If no history exists then 1 negative cotinine level must be submitted

Refusal or failure to undergo monthly testing for those members with a history of alcohol, tobacco, and/or drug use will be interpreted as a positive test result.

Six month abstinence period may be shortened in cases where patient's condition is sufficiently advanced that mortality is reasonably expected before the full abstinence period can be completed. Patients granted a waiver of the six month abstinence period require documentation of participation in a formal outpatient treatment program, when practical, as well as serial blood or urine testing no less frequently than monthly. A positive test result at any time prior to the procurement phase will result in denial.

Requested information for referral of a potential heart transplant candidate:
(See attachment, Table 1)

Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2019, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

CPT®* Codes	Description
33945	Heart Transplantation, with or without recipient cardiectomy

HCPCS ®* Codes	Description

ICD-10-CM Diagnosis Codes that Support Coverage Criteria

+ Indicates a code(s) requiring an additional character

ICD-10-CM Code	Description

Reviews, Revisions, and Approvals	Revisions Date	Approval Date
Original approval date		2/11/13
Annual Review with no changes		12/2020
Annual Review	12/21	12/21

References

1. Mandeep R. Mehra, MD (Chair), Charles E. Canter, MD, Margaret M. Hannan, MD , et al. The 2016 International Society for Heart Lung Transplantation listing criteria for heart transplantation: A 10-year update. The Journal of Heart and Lung Transplantation. January

2016. Ward, Slutsker, Buehler, Jaffe, Berkelman, & Curran. 1993 Revised Classification System for HIV infection and Expanded Surveillance Case Definition for Aids Among Adolescents and Adults. *Center for Disease Control* (12/18/1992)
2. State of Illinois Contract between the Department of Healthcare and Family Services and Meridian Health Plan of Illinois, 2018-24-601, Preauthorization and Concurrent Review Requirements, 1.1.2.3.3
3. American College of Cardiology Foundation, American Heart Association Task Force on Practice Guidelines *Circulation*, April 14, 2009.
4. Kim et al. Refractory angina pectoris. J Am Coll Cardiol 2002; 39(6): 923-934).

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members/enrollees and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members/enrollees and their representatives agree to be bound by such terms and conditions by providing services to members/enrollees and/or submitting claims for payment for such services.

Note: For Medicaid members/enrollees, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.