Molina Clinical Policy
Heart Transplantation: Policy No. 116

Last Approval: 12/11/2024
Next Review Due By: December 2025

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Heart failure affects over 6.7 million adults annually in the United States and between 12,000 to 35,000 children under age 19 (CDC 2024; Singh & Singh 2022). The leading causes of heart failure in adults are nonischemic cardiomyopathy and coronary artery disease, however, an increasing portion of adult heart transplants are due to complex congenital heart disease, restrictive cardiomyopathies, hypertrophic cardiomyopathies, and those requiring re-transplantation. In children, the most common disease processes leading to heart transplant are cardiomyopathy resulting in end stage heart failure, and congenital heart disease refractory to medical or conventional surgical treatment.

Heart transplantation is the last life saving measure available to those with end stage heart failure refractory to conventional medical management. In 2022, of the 42,888 transplants performed in the United States, approximately 10% were heart transplants, which is a sharp increase compared to 2021 (Mancini 2024).

In the adult population, median survival following heart transplantation is 11 years. Among pediatric transplant recipients, the median survival post-transplant ranges from 13 years among adolescents to 22 years for infant recipients. The highest mortality rate remains the first-year post-transplant. Causes of death within the first year following heart transplant include primary graft failure, infections, and rejection; thereafter mortality is contributed to cardiac allograft vasculopathy, non-specific graft failure, and malignancies. Approximately 3% of recipients undergo re-transplantation; selection criteria are high for those with graft failure (Pham 2024).

Advances in immunosuppression and transplantation have improved survival rates in heart transplant recipients, however hospitalizations for organ rejection and/or infection occur in 30-40% of patients within three years post-transplant (Singh & Singh 2022). In those who survive heart transplantation, many regain much of their functional status, with moderate to minor limitations in strenuous activities. The pediatric population fairs the best in reaching function status by having a three-year post-transplant functional status of 80%, which includes normal activity or minor limitations in strenuous activity.

Heart Allocation Process

The time in which a patient is on a pre-transplant waitlist has decreased since 2005. Updates to the organ allocation system have been one improvement along with success in transplant candidate survival when supported with ventricular assist devices. Currently transplant candidates are assigned a status which signals health condition and medical need for an organ based on a variety of factors, such as mechanical support, ECMO (extracorporeal membrane oxygenation) dependency, inotrope usage and more. Adults are assigned a status 1 – 6, and pediatric patients are assigned status 1A, 1B, or 2 (OPTN 2024).

The United Network for Organ Sharing (UNOS) allocation system was updated from a three-level system to a six-tier system in October 2018 and is currently developing a continuous distribution process for hearts. The continuous distribution framework gives candidates a composite score which more accurately reflects their status, instead of the current method which heavily relies on categories and sometimes misses candidates in dire need. The continuous distribution framework ensures no single factor/category determines priority for organs (UNOS 2024).

RELATED POLICIES

MCP-459 Pre-Transplant and Transplant Evaluation
MCP-245: Heart Transplantation with a Total Artificial Heart

COVERAGE POLICY

All transplants require prior authorization from the Corporate Transplant Department. The Corporate Senior Medical Director or qualified clinical designee will review solid organ transplant requests. All other transplants will be reviewed by the Corporate Senior Medical Director or covering Medical Director. If the criteria are met using appropriate NCD and/or LCD guidelines, State regulations, and/or MCP policies the Corporate Senior Medical Director's designee can approve the requested transplant.

Office visits with participating Providers do NOT require prior authorization. Providers should see the Member in office visits as soon as possible and without delay. Failure to see the Member in office visits may be considered a serious quality of care concern.

Please see MCP-459 Pre-Transplant and Transplant Evaluation for pre-transplant criteria and transplant evaluation criteria that must be met prior to solid organ transplant.

Adult Criteria for Transplantation

Heart Organ transplantation from a deceased donor may be **considered medically necessary** in Members who are age 18 years or older who meet **ALL** the following criteria:

1. All pre-transplant and transplant evaluation criteria are met
2. Heart failure prognosis scores performed with cardiopulmonary exercise test to determine prognosis and guide listing for transplantation for ambulatory patients. (Acceptable cut points for listing should be based on an estimated one-year survival as calculated by the Seattle Heart Failure Model of < 80% OR a Heart Failure Survival Score in the high/medium risk range)
3. Member meets **ONE** of the following indications for cardiac transplantation:
   a. Cardiogenic shock (defined as decreased cardiac output and evidence of tissue hypoxia in the presence of adequate intravascular volume despite maximum medical therapy)
   b. Severe heart failure (New York Heart Association Class IV) that requires continuous intravenous inotropic support or mechanical cardiac support (such as intra-aortic balloon pump).
      i. Includes sustained hypotension (systolic blood pressure < 90 mm Hg for at least 30 min) and a reduced cardiac index (< 2.2 L/min/m^2) in the presence of elevated pulmonary capillary wedge pressure (>15 mmHg)
   c. Severe chronic heart failure as indicated by **ALL** the following:
      i. NYHA Class III or IV (despite maximal medical therapy)
      ii. Peak VO_2 on cardiopulmonary exercise test of $\leq$ 14 mL/kg/min OR $\leq$ 12 mL/kg/min if patient is on a beta-blocker
   d. Severe cardiac ischemia (angina) despite maximal feasible therapy (revascularization and/or medication) and consistently limits routine activity that is not amenable to coronary artery bypass surgery or angioplasty
   e. Recurrent symptomatic or life-threatening ventricular arrhythmia unresponsive to therapy and interventional procedures such as intracardiac defibrillator or catheter ablation
   f. Low grade myocardial tumor with **ALL** the following:
      i. No evidence of metastatic disease
      ii. Tumor is unresectable

g. Selected patients with restrictive and hypertrophic cardiomyopathies including cardiac amyloidosis
h. Unresectable ventricular diverticula
i. Re-transplant is requested for graft dysfunction due to severe allograft vasculopathy
j. Severe congenital heart disease as indicated by at least **ONE** of the following:
    i. Severe symptomatic cyanotic heart disease not amenable to palliation
    ii. Single ventricle physiology
    iii. Post-Fontan procedure with refractory heart failure, persistent protein-losing enteropathy, and/or plastic bronchitis despite optimal medical and surgical therapy
    iv. Eisenmenger syndrome
    v. Reactive pulmonary hypertension with risk for progression to a level of fixed pulmonary vascular resistance that may preclude future transplant
    vi. Ventricular failure due to complex congenital heart disease that is not amenable to other surgical alternatives
    vii. Severe oxygen desaturations not amenable to other surgical correction
    viii. Severe heart failure refractory to medical therapy not amenable to other surgical, interventional, or electrophysiologic intervention

4. Documentation that all medical, pharmaceutical, and surgical alternatives to transplant have been utilized, if applicable, including but not limited to:
    a. Alcohol septal ablation, myomectomy, mitral valve replacement, maximal medical therapy, or pacemaker therapy in patients with cardiomyopathy
    b. Failed previous surgical correction or condition is not amendable to surgery in patients with congenital heart disease
    c. Percutaneous coronary intervention or not amenable to coronary artery bypass surgery in patients with coronary artery disease
    d. Valve replacement or repair in patients with valvular disease
    e. Low sodium diet, diuretics, fluid restriction for patients with congestive heart failure
    f. Pacing cardioverter defibrillator, electrophysiology guided single- or combination medical therapy, or not a candidate for ablative therapy in patients with arrhythmias
    g. Coronary artery bypass surgery or percutaneous coronary intervention in patients with severe angina

5. In addition to the relative contraindications in MCP-459 Pre-Transplant and Transplant Evaluation, the requesting transplant recipient is carefully evaluated and potentially treated for any of the following organ specific relative contraindications:
    a. Multisystem disease with severe extracardiac organ dysfunction
    b. Active infection (patients may be considered for a transplant with well-controlled chronic infections such as HIV and Hepatitis C and B, with undetectable titers and no end-organ damage)
    c. Advanced kidney disease requires consultation by a nephrologist
    d. Recent pulmonary embolism requiring anticoagulation (within the last 3-6 months)
    e. Severe pulmonary hypertension (PH), if PH is refractory to medical therapy, then it is an absolute contraindication to heart transplant

Pediatric Criteria for Transplantation

Heart Organ transplantation from a deceased donor may be **considered medically necessary** in Members who are under the age of 18 years who meet **ALL** the following criteria:

1. End stage heart failure with persistent symptoms at rest who require at least ONE of the following:
    a. Continuous infusion of intravenous inotropic agent
    b. Mechanical ventilatory support
    c. Mechanical circulatory support

2. Member meets **ONE** of the following indications for cardiac transplantation:
    a. Stage D heart failure associated with systemic ventricular dysfunction in pediatric patients with cardiomyopathies or previously repaired or palliated CHD (e.g., continuous intravenous inotropic support or mechanical circulatory support is required)
    b. Stage C heart failure (with present or history of symptomatic heart failure) **AND** one or more of the following:

i. Maximal oxygen consumption on cardiopulmonary exercise testing (less than 50% of expected level for age/sex)
ii. Heart-disease related growth failure
iii. Recurrent symptomatic or life-threatening arrhythmia unresponsive to medical therapy and interventional procedures (e.g., catheter ablation, intracardiac defibrillator)
iv. Severe exercise or activity intolerance
v. Progressive pulmonary hypertension

c. Stage C heart failure in pediatric heart disease with associated near sudden death and/or life-threatening arrhythmias untreatable with medications or an implantable defibrillator
d. Stage C heart failure in pediatric restrictive cardiomyopathy disease associated with reactive pulmonary hypertension
e. Stage C heart failure in pediatric heart disease associated with reactive pulmonary hypertension and a potential risk of developing fixed, irreversible elevation of pulmonary vascular resistance that could preclude orthotopic heart transplantation in the future
f. Severe congenital heart disease with <u>at least one</u> of the following:
    i. Hypoplastic left heart syndrome and 1 or more of the following:
        1. Proximal coronary artery stenosis or atresia
        2. Atrioventricular or semilunar valve with moderate to severe stenosis or insufficiency
        3. Severe ventricular dysfunction including heart failure associated with systemic ventricular dysfunction in patients with cardiomyopathies or previously repaired/palliated CHD when heart failure is associated with significant growth failure attributable to the heart disease
    ii. Severe arterial oxygen desaturations (cyanosis) not amenable to other surgical correction
    iii. Fontan circulation with systemic complications with <u>at least one</u> of the following:
        1. Protein losing enteropathy
        2. Plastic bronchitis
        3. Stroke or thromboembolic disease
        4. Cirrhosis of the liver
        5. Refractory ascites
    iv. Failed surgical palliation
g. Low-grade myocardial tumor and **ALL** the following:
    i. No evidence of metastatic disease
    ii. Tumor is unresectable
h. Re-transplant is requested for graft dysfunction due to severe allograft vasculopathy

3. Documentation should be submitted as outlined above in the Adult Criteria

4. The requesting transplant recipient is free of all <u>absolute contraindications</u> as outlined in MCP 459 Pre-Transplant and Transplant Evaluation

5. In addition to the relative contraindications in MCP-459 Pre-Transplant and Transplant Evaluation, the requesting transplant recipient is carefully evaluated and potentially treated for any of the organ specific <u>relative contraindications</u> as outlined above in the Adult Criteria #5

<u>Re-Transplantation</u>

A second transplant may be **considered medically necessary** when **ALL** the other requirements for transplantation outlined above have been met **AND** <u>one</u> of the following conditions are present:
1. Graft failure of an initial heart transplant due to either technical reasons or acute rejection
2. Chronic rejection
3. Significant cardiac allograft vasculopathy with refractory cardiac allograft dysfunction, without evidence of ongoing acute rejection
4. Recurrent disease

<u>Heart and Lung Transplantation</u>

For multi-organ transplant requests, criteria must be met for each organ requested.

Limitations and Exclusions

1. Requests for a third or subsequent heart transplant are **NOT considered medically necessary**.

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

National and Specialty Organizations

The **Organ Procurement and Transplantation Network (OPTN)** published *Policy 6: Allocation of Hearts and Heart-Lungs* which includes adult and pediatric status assignments and updated requirements; adult and pediatric status exceptions; waiting time; and heart allocation classifications and rankings (OPTN 2024).

The **International Society for Heart Lung Transplantation (ISHLT)** published 2024 *Guidelines for the Evaluation and Care of Cardiac Transplant Candidates* (Peled et al. 2024) which comprehensively addresses multiples aspects of the medical care needed in heart transplant candidates. Section include evaluation for heart transplant candidacy, optimization of the medical surveillance of patients on the waitlist, and considerations for mechanical circulatory support systems. The guidelines grade recommendations based on strength of evidence and address, in detail, special considerations based on age, co-morbidities, and special populations.

The **American College of Cardiology (ACC) and American Heart Association (AHA)** published the updated the following guidelines pertaining to heart failure and heart transplant:

- *2024 Update to the 2020 ACC/AHA Clinical Performance and Quality Measures for Adults With Heart Failure: A Report of the American Heart Association/American College of Cardiology Joint Committee on Performance Measures* (Kittleson et al. 2024) which lays our performance measures for heart failure
- *2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology / American Heart Association Joint Committee on Clinical Practice Guidelines* (Heidenreich et al. 2022) which provides clinical recommendations to prevent, diagnose, and manage patients with heart failure.
- *2021 ACC/AHA Key Data Elements and Definitions for Heart Failure* (Bozkurt et al. 2021) provides a consistent clinical lexicon, data elements for heart failure risk factors, patient assessment, diagnostic modalities and more.

SUPPLEMENTAL INFORMATION

New York Heart Association Functional Classification (AHA 2023):

I. No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, or shortness of breath.
II. Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, shortness of breath or chest pain.
III. Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, shortness of breath or chest pain.
IV. Symptoms of heart failure at rest. Any physical activity causes further discomfort.

CODING & BILLING INFORMATION

CMS has a National Coverage Determination (NCD) *Heart Transplantation (260.9)* which covers the procedure in adults when performed in a facility which is approved by Medicare as meeting institutional coverage criteria. Pediatric heart transplantation is covered when performed in a pediatric hospital that performs pediatric heart transplants if the hospital submits an application which CMS approves as documenting that:

- The hospital's pediatric heart transplant program is operated jointly by the hospital and another facility that has been found by CMS to meet the institutional coverage criteria in CMS Ruling 87-1.

- The unified program shares the same transplant surgeons and quality assurance program (including oversight committee, patient protocol, and patient selection criteria); and
- The hospital can provide the specialized facilities, services, and personnel required by pediatric heart transplant patients.

CPT (Current Procedural Terminology)

Code	Description
33930	Donor cardiectomy-pneumonectomy (including cold preservation)
33933	Backbench standard preparation of cadaver donor heart/lung allograft prior to transplantation, including dissection of allograft from surrounding soft tissues to prepare aorta, superior vena cava, inferior vena cava, and trachea for implantation
33935	Heart-lung transplant with recipient cardiectomy-pneumonectomy
33940	Donor cardiectomy (including cold preservation)
33944	Backbench standard preparation of cadaver donor heart allograft prior to transplantation, including dissection of allograft from surrounding soft tissues to prepare aorta, superior vena cava, inferior vena cava, pulmonary artery, and left atrium for implantation
33945	Heart transplant, with or without recipient cardiectomy

HCPCS (Healthcare Common Procedure Coding System)

Code	Description
S2152	Solid organs(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 post-transplant care in the global definition

APPROVAL HISTORY

12/11/2024	Policy reviewed. Coverage criteria updated with removal of redundant criteria points of reduced exercise capacity and dependent on IV inotropes under criteria #3. Pediatric absolute and relative contraindications clarified with reference to MCP 459 pre-transplant and transplant evaluation. IRO Peer Reviewed on November 19, 2024, by a practicing physician board certified in Transplant Surgery and Vascular Surgery.
06/12/2024	Coverage criteria revised with removal of transplant evaluation, continuation of therapy, and general contraindication coverage criteria as it is now stipulated in MCP 459 Pre-Transplant and General Transplant Evaluation. Annual Review Scheduled for Feb 2025.
02/14/2024	Policy reviewed, changes to criteria include age for colonoscopy reduced to 45 years, addition of non-life limiting neurological impairment criteria and additional disease processes to criteria, removal of abnormal serology criteria and daily cannabis use section, and addition of active pregnancy and substance abuse statement under absolute contraindications. IRO Peer Review on January 4, 2024, by a practicing physician board certified in Cardiovascular Disease.
02/08/2023	Policy reviewed, no changes to criteria, included section on cannabis use.
02/09/2022	Policy reviewed; updated items from 2016 ISHLT criteria; included marijuana use under absolute contraindications; updated Summary of Medical Evidence and Reference sections. IRO Peer Review on February 7, 2022, by a practicing physician board certified in General Surgery, Transplant Surgery.
02/08/2021	Policy reviewed. No changes to coverage criteria, updated overview and summary of medical evidence.
04/23/2020	Policy reviewed. No changes to coverage criteria, updated overview and summary of medical evidence.
09/18/2019	Policy reviewed. No changes to coverage criteria, updated overview and summary of medical evidence.
09/13/2018	Policy reviewed. Added criteria for restrictive and hypertrophic cardiomyopathies, and congenital heart disease (adults); updated pretransplant criteria to include significant cardiac allograft vasculopathy with refractory cardiac allograft dysfunction, without evidence of ongoing acute rejection. Added multisystem disease with severe extracardiac organ dysfunction as an absolute contraindication to transplant. Updated professional society guidelines and references.
06/22/2017	Policy reviewed. No changes to coverage criteria, updated overview and summary of medical evidence.
09/15/2016	Policy reviewed. No changes to coverage criteria, updated overview and summary of medical evidence.
04/09/2015	Policy reviewed; updated with new pretransplant criteria; condensed medical evidence section.
09/24/2012	New policy.

REFERENCES

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