Molina Clinical Policy
Heart Transplantation and Heart Transplantation with a Total Artificial Heart
Policy No. 116

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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 (HF) 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 2025). The leading causes of HF 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 HF, and congenital heart disease refractory to medical or conventional surgical treatment (Mancini 2024; Singh & Singh 2025).

Heart transplantation is the treatment of choice for many patients with end-stage HF refractory to conventional medical management. In 2024, of the 48,149 transplants performed in the United States, approximately 10% were heart transplants. Although barriers still exist, long-term survival for transplant recipients has improved over the last few decades due to advances in recipient and donor selection, immunosuppression, and the prevention and treatment of opportunistic infections ([2]OPTN 2025; Pham 2024).

In adults, median survival following heart transplantation is over 12 years. Among pediatric recipients, the median survival post-transplant ranges from 13 years in adolescents to 22 years in infants (Dipchand & Laks 2019; Pham 2024). The highest mortality rate remains the first-year post-transplant. Causes of death within the first year typically 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, and selection criteria are stringent for those with graft failure (Pham 2024).

While advances have improved survival rates, treatment for organ rejection occurs in roughly 23% of patients within the first year post heart transplant, and the incidence of infection ranges from 30-80% (Gemelli et al. 2023; Zhou et al. 2021). Following heart transplantation, over 70% of patients regain much of their functional status, with moderate to minor limitations in strenuous activities (Pham 2024). The pediatric population fares the best in reaching excellent function status, where most children who survive at least one year following heart transplant are highly active without significant limitations (Peng et al. 2017).

The time in which an adult patient is on a heart pre-transplant waitlist has decreased since 2018, largely due to updates to the organ allocation system. Improved survival among candidates supported with ventricular assist devices (VAD) has also reduced waitlist mortality (Colvin et al. 2025). Currently, transplant candidates are assigned a status which signals their health condition and medical need for an organ based on a variety of factors, such as mechanical support dependency (extracorporeal membrane oxygenation [ECMO], VAD, intra-aortic balloon pump), hemodynamic stability, HF severity, end-organ function indicators, sensitization risk, and other clinical indicators. Adults are assigned a status from 1 through 6, while pediatric patients are assigned status 1A, 1B, or 2 ([1]OPTN 2025).

In 2018, the United Network for Organ Sharing (UNOS) updated the **adult heart allocation system** from a three-tier system to a six-tier system, while pediatric heart candidates still use a three-tier system. Additionally, UNOS and the Organ Procurement and Transplantation Network (OPTN) are developing a continuous distribution framework for hearts, which will replace the current classification-based system with a composite allocation score system, which aims to more accurately determine priority by considering multiple factors, such as medical urgency, expected post-transplant survival, candidate biology, proximity, and placement efficiency. This approach aims to ensure that no single factor disproportionately determines organ allocation priority (OPTN date unknown).

A **temporary total artificial heart (TAH-t)** is an implantable, pneumatic, biventricular support device that provides a total replacement for both ventricles of the failing heart. The implantation of a total artificial heart is used as a bridge to transplantation in patients with end-stage heart failure who meet standard, accepted criteria for heart transplantation, are at imminent risk of death with no other treatment options, and for whom a compatible donor heart is unavailable. The TAH is powered by an external battery powered driver system that delivers air in pulses to the heart's ventricles, closely replicating the natural pumping action of a human heart. The volume of TAH implantations is very low, with fewer than 100 cases per year in the United States (Mancini and Anyanwu 2024).

Regulatory Status

The SynCardia temporary Total Artificial Heart TAH-t, formerly referred to as the CardioWest Total Artificial Heart, is the only FDA-approved device for a bridge to transplant in cardiac transplant-eligible candidates at risk of imminent death from biventricular failure, intended and approved for use inside the hospital. The initial Syncardia TAH was approved on October 14, 2004. This 70cc TAH was indicated for patients with a T10* measurement ≥ 10cm. On March 5, 2020, Syncardia received approval for the 50cc TAH. This device is for patients with adequate T10 measurement or adequate room in the chest as determined by imaging or other clinical assessments. These patients typically have a BSA ≤1.852. SynCardia's temporary TAH-t system is regulated by the FDA under the product code LOZ in the Premarket Approval database.

*Posterior sternum to anterior spine measurement at T10

RELATED POLICIES

MCP-459 Pre-Transplant and Transplant Evaluation
MCP-115: Lung Transplantation

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 Heart Transplantation

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

1. All pre-transplant and transplant evaluation criteria are met as stipulated in MCP-459

2. Heart failure (HF) prognosis score performed with cardiopulmonary exercise testing to assess prognosis and guide listing for ambulatory patients (e.g., Seattle Heart Failure Model estimated 1-year survival < 85% or a Heart Failure Survival Score of medium to high risk)

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 HF (New York Heart Association [NYHA] Class IV) that requires continuous intravenous inotropic support or mechanical circulatory support
        i. Includes sustained hypotension (systolic blood pressure < 90 mm Hg for ≥ 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 HF 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 ≤ 14 mL/kg/min OR ≤ 12 mL/kg/min if on beta-blocker
    d. Severe cardiac ischemia despite maximum medical and/or revascularization therapy that consistently limits routine activity and is not amenable to further revascularization
    e. Recurrent symptomatic or life-threatening ventricular arrhythmia unresponsive to medical and interventional therapies (e.g., implantable cardioverter-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 Members with restrictive or hypertrophic cardiomyopathies, including those due to cardiac amyloidosis with limited extracardiac involvement
    h. Unresectable ventricular diverticula
    i. Re-transplant is requested for graft dysfunction due to severe allograft vasculopathy
    j. Severe congenital heart disease (CHD) 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 HF, persistent protein-losing enteropathy, and/or plastic bronchitis despite optimal medical and surgical therapy
        iv. Eisenmenger syndrome
        v. Reactive pulmonary hypertension (PH) with risk for progression to a level of fixed pulmonary vascular resistance that may preclude future transplant
        vi. Ventricular failure due to complex CHD that is not amenable to other surgical alternatives
        vii. Severe oxygen desaturations not amenable to other surgical correction
        viii. Severe HF 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 Members with cardiomyopathy
    b. Failed previous surgical correction or condition not amenable to surgery in Members with CHD
    c. Percutaneous coronary intervention or condition not amenable to coronary artery bypass surgery in Members with coronary artery disease
    d. Valve replacement or repair in Members with valvular disease
    e. Low sodium diet, diuretics, and fluid restriction in Members with congestive HF

f. Implantable cardioverter-defibrillator, electrophysiology-guided medical therapy, or condition not amenable to ablative therapy, in Members with arrhythmias
g. Coronary artery bypass surgery or percutaneous coronary intervention in Members with severe cardiac ischemia

5. In addition to the absolute and relative contraindications outlined in MCP-459, the Member 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 (Member 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 PH (if PH is refractory to medical therapy then it is an absolute contraindication to heart transplant)
   f. Severe, symptomatic peripheral vascular disease (e.g., disabling claudication not amenable to revascularization or nonhealing ischemic ulcers)
   g. Connective tissue disease expected to shorten post-transplant survival, associated with severe extracardiac disease, or uncontrolled with pre-transplant immunosuppression

Pediatric Criteria for Heart Transplantation

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

1. End-stage HF with persistent symptoms at rest that requires 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 HF associated with systemic ventricular dysfunction with cardiomyopathies or previously repaired or palliated CHD (e.g., continuous intravenous inotropic support or mechanical circulatory support is required)
   b. Stage C HF and at least ONE of the following:
      i. Maximal oxygen consumption on cardiopulmonary exercise testing (VO_2 < 50% of expected level for age, size, and muscle mass)
      ii. Heart disease-related growth failure
      iii. Recurrent symptomatic or life-threatening arrhythmia (including near-sudden death) unresponsive to medical and interventional therapies (e.g., catheter ablation, implantable cardioverter-defibrillator)
      iv. Severe exercise or activity intolerance
      v. Pediatric heart disease (including restrictive cardiomyopathy) associated with reactive PH at risk of progressing to fixed, irreversible elevation of pulmonary vascular resistance that could preclude orthotopic heart transplantation in the future
   c. Severe CHD with at least ONE of the following:
      i. Hypoplastic left heart syndrome and at least ONE 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 HF associated with systemic ventricular dysfunction in patients with cardiomyopathies or previously repaired/palliated CHD when HF is associated with significant growth failure attributable to heart disease
      ii. Severe arterial oxygen desaturations (cyanosis) not amenable to other surgical or interventional correction
      iii. Fontan circulation with systemic complications with at least ONE 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

d. Low-grade myocardial tumor and ALL the following:
   i. No evidence of metastatic disease
   ii. Tumor is unresectable
e. Re-transplant is requested for graft dysfunction due to severe allograft vasculopathy

3. Documentation should be submitted as outlined above in Adult Criteria for Heart Transplantation, criteria #4

4. In addition to absolute and relative contraindications outlined in MCP-459, Member is carefully evaluated and potentially treated for any organ-specific relative contraindications, as outlined above in criteria #5 of the Adult Criteria for Heart Transplantation

Adult and Pediatric Criteria for Re-Transplantation

A second transplant may be **considered medically necessary** when *ALL the other requirements for transplantation outlined above have been met* and ONE of the following conditions is 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

Requests for a third or subsequent heart transplantation are **not considered medically necessary** and will not be authorized

Heart and Lung Transplantation

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

Heart Transplant with a Total Artificial Heart

The SynCardia temporary Total Artificial Heart (TAH-t) System may be **considered medically necessary** as a bridge to heart transplantation when ALL the following criteria are met:

1. Member meets ALL Adult or Pediatric heart transplant criteria stipulated above and is eligible for an immediate donor heart transplant

2. Member is ineligible for other univentricular or biventricular support devices

3. Member has no other reasonable medical or surgical treatment options

4. Temporary artificial heart to be used in accordance with FDA label

5. Member is in imminent danger of dying within 48 hours or at risk of becoming ineligible for transplant

6. Member meets the criteria of New York Heart Association Functional Class IV

7. Member has a diagnosis of biventricular failure and rapid decompensation

8. There is an unavailability of heart donor and likelihood that Member's condition will deteriorate before a donor can be identified

9. Member has absent thrombophilia and can be adequately anticoagulated on the SynCardia temporary Total Artificial Heart (TAH-t) System

The SynCardia temporary Total Artificial Heart (TAH-t) System is considered **experimental, investigational, and unproven** for permanent use as destination therapy and should only be used in an approved heart transplant facility

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

SynCardia Total Artificial Heart

Non-Randomized Studies, Retrospective Reviews, and Other Evidence

Razumov et al. (2024) performed a retrospective analysis of 196 patients who received total artificial heart (TAH) replacements. The main goals of the study were to assess survival rates and identify factors predicting mortality during TAH support. Secondary outcomes focused on adverse events and survival rates post-heart transplantation. The survival rates at 1, 6, and 12 months were reported as 72%, 41%, and 34%, respectively. The cumulative incidence of heart transplantation while on TAH support was 1% at 1 month, 11% at 6 months, and 23% at 1 year. Adverse events documented included postoperative rethoracotomy (44.4%), neurological complications (64.8%), and gastrointestinal bleeding (24.6%). A total of 35.2% of patients successfully underwent heart transplantation with a median posttransplant survival time of 5.8 years. Post-transplant survival rates at 1, 5, and 10 years were 65%, 58%, and 51%, respectively. Despite the high mortality associated with biventricular failure, the SynCardia TAH remains a viable temporary option for critically ill patients, especially those who can be bridged to heart transplantation.

Itagaki et al. (2022) queried the United Network of Organ Sharing Standard Transplant Research File between 2005 and 2018 for data from total artificial heart transplants and ran the data through multivariable Cox regression models for risk prediction. The data revealed a total of 471 patients underwent total artificial heart implantation. The 6-month cumulative incidence of mortality on the total artificial heart was 24.6%, paired with a 49% 6-month cumulative incidence of heart transplant. Of 161 transplant centers, 11 centers had cumulative volume of 10 or more implants. Cumulative center volume less than 10 implants were predictive of both mortality on the total artificial heart (hazard ratio, 2.2, 95% confidence interval, 1.5-3.1, $P < .001$) and post-transplant mortality after a total artificial heart bridge (hazard ratio, 1.5, 95% confidence interval, 1.0-2.2, $P = .039$). In summation the data indicated that total artificial heart is a viable bridge to heart transplantation, especially in higher volume centers. The revelation of inferior outcomes in lower volume centers indicates targeted training, center certifications, and minimum volume requirements could improve outcomes for patients requiring the total artificial heart.

Chen et al. (2022) queried the United Network of Organ Sharing Standard Transplant Research File between 2005 and 2020 to compare the 392 adults who underwent heart transplantation after receiving the total artificial heart as a bridge treatment (TAH-t BTT) against 11,014 durable left ventricular assist device bridge to transplantation (LVAD BTT) patients and 22,348 de novo heart transplants during the same period in the United States. The data revealed that patients who received TAH-t BTT patients had increased dialysis dependence compared to LVAD BTT and de novo transplants (24.7% vs. 2.7% vs. 3.8%) and higher levels of baseline creatinine and total bilirubin (all $p < .001$). After heart transplantation, TAH-t BTT patients were more likely to die from multiorgan failure in the first year (25.0% vs. 16.1% vs. 16.1%, $p = .04$); however, of those who survived the first-year post-transplant the 10-year survival rate was similar across the board (TAH-t BTT 66.8%, LVAD BTT 68.7%, De Novo 69.0%, all $p > .20$). Among TAH-t BTT

patients, predictors of 1-year mortality included higher baseline creatinine and total bilirubin, mechanical ventilation, and cumulative center volume <20 cases of heart transplantation involving TAH-t BTT (all p < .05). TAH-t BTT survival rates are acceptable, better at higher volume centers, and the patients who survive the first-year post heart transplantation face similar mortality risks over time when compared to LVAD BTT and de novo heart transplant recipients.

Carrier et al. (2021) conducted a retrospective analysis of 217 consecutive patients who received total artificial heart transplants as a bridge to heart transplantation from 2014 – 2019 in six high volume North American centers. Of the 217 total artificial heart transplants 138 underwent heart transplant, while 75 (34.5%) died before they could receive a heart transplant. The mean time between total artificial heart transplant and heart transplant averaged 181 ± 179 days (range: 0-849) and the mean follow-up after heart transplant was 35 ± 25 months. The overall survival in the entire cohort was 75%, 64%, and 58% at 1, 2, and 5 years, respectively. Post-transplant survival was 88%, 84%, 79%, and 74% at 6 months, 1 year, 2 years, and 5 years, respectively. In summation, almost two thirds of those who received a total artificial heart could be transplanted with overall and post heart transplantation satisfactory survival rates.

Villa et al. (2020) evaluated the use of the SynCardia TAH in pediatric patients with end stage biventricular heart failure. The study included 51 children and adolescents who received the device as a bridge to cardiac transplantation. 36 patients received the 70cc device and 15 received the 50cc device. The average support duration was 145 days and 113 days for 50 cc and 70cc TAH patients, respectively. The majority of patients were supported for 6 months or less. Overall survival was reported at 71%, with a total of 35 patients being successfully supported transplantation. The study highlights that the introduction of the 50cc TAH model has significantly expanded access to mechanical circulatory support for smaller patients, particularly those with the body surface area BSA less than 1.7 M^2. It also emphasizes the importance of anatomical fit assessments, including T10 measurement and 3D imaging in determining device suitability. The authors conclude that the TAH is a viable and increasingly effective bridge to transplantation in pediatric populations, with advances in device sizing and imaging techniques contributing to improved access and outcomes.

Morshuis et al. (2020) conducted a retrospective analysis of 193 patients who received a total artificial heart as a bridge to transplantation (TAH-t BTT) at a high-volume German center from 2001 – 2019. The 69 TAH-t BTT patients who received heart transplants were compared to 393 left ventricular assist device bridge to transplantation (LVAD BTT), 70 biventricular assist device bridge to transplantation (BVAD BTT), and 876 de novo heart transplantation conducted at the same center. Total survival rates after heart transplantation were 43.5% for TAH-t BTT, 60% for BVAD BTT, 61.1% for LVAD BTT, and 60% for de novo heart transplants; however, the highest mortality rates for TAH-t BTT happened within one year post heart transplant, of those that survived the first year the survival rates were not significantly different from all other post-transplant survival rates. The authors offered possible reasons for the significant difference in the first year mortality of TAH-t BTT patients including significantly increased adhesions due to the device, prolonged surgical preparation times leading to prolonged cold and warm ischemic times, and the inability to completely evaluate SynCardia TAH patients for transplantation due to the device not allowing for certain measurements such as pulmonary artery pressures and such, thus possibly covering up underlying significant vascular disease prior to transplantation. All these potential factors kept in mind; the authors concluded that TAH-t BTT is a viable option for patients when vigorous risk assessments are made on a case-by-case basis.

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. The policy also includes adult and pediatric status exceptions, waiting times, and heart allocation classifications and rankings. When registering a transplant candidate to the OPTN, the following clinical data must be submitted: current diagnosis, hemodynamic assessment results, functional status or exercise test results, heart failure (HF) severity or end organ function, heart failure therapies, mechanical support, and sensitization risk (e.g., calculated panel reactive antibodies [PRA], peak PRA, and the number of prior sternotomies) ([1]OPTN 2025).

The **International Society for Heart and Lung Transplantation (ISHLT)** published 2024 *Guidelines for the Evaluation and Care of Cardiac Transplant Candidates*, which comprehensively addresses multiple aspects of the medical care needed in heart transplant candidates. The guidelines grade recommendations based on strength of

evidence and address, in detail, special considerations based on age, co-morbidities, and special populations. The authors note there have been significant practice-changing developments in the evaluation and care of heart transplant recipients since previously published guidelines, primarily involving patient selection criteria, care, and mechanical support (Peled et al. 2024).

The ISHLT outlines the most common indications for heart transplant, which include highly symptomatic HF, cardiogenic shock, and uncontrolled ventricular arrhythmias. Other less common indications include restrictive cardiomyopathies and complex congenital heart disease (CHD) when surgical palliation has failed. The authors note that it's essential to thoroughly evaluate a patient's clinical situation to determine whether it's limited enough to warrant transplantation. This requires confirmation that all attempts to optimize cardiac function have been exhausted (e.g., using optimal medical therapy and interventions such as cardiac resynchronization therapy and transcatheter mitral valve repair when indicated). Clinical indicators, HF prognosis scores, cardiopulmonary exercise tests, and right heart catheterization are ways to evaluate and identify advanced HF (Peled et al 2024).

The ISHLT made the following recommendations regarding indications for heart transplantation (Peled et al. 2024):

- In patients with HF and when consistent with the patient's goals of care, the presence of clinical indicators of advanced HF should trigger evaluation for advanced HF therapies, including heart transplantation (Class 1 [Strong] recommendation based on moderate-quality evidence)
- In ambulatory adult patients with HF who have been referred for transplant evaluation (and in age-appropriate pediatric patients), cardiopulmonary exercise tests should be routinely performed to determine prognosis, quantify exercise intolerance, and guide listing (Class 1 [Strong] recommendation based on moderate-quality evidence)
- In adult patients with HF who are being evaluated for transplantation, a right heart catheterization should be performed prior to transplant listing to assess for pulmonary hypertension and for cardiogenic shock that requires inotropic support and/or temporary mechanical circulatory support (Class 1 [Strong] recommendation based on limited data)
    - For pediatric heart transplant candidates, right heart catheterization may be performed prior to listing (Class 2b [Weak] recommendation based on expert opinion)
- In adult heart transplant candidates, "HF prognosis scores can be considered in the context of other data collected during transplant evaluation to guide listing decisions" (Class 2a [Weak] recommendation based on limited data)

According to the ISHLT, the presence of one or more clinical signs or symptoms of advanced HF is associated with worse prognosis, and therefore recognition of these signs or symptoms should prompt timely referral. The following risk factors have been proven to increase all-cause mortality in HF patients: previous or current inotrope use, New York Heart Association (NYHA) class III or IV and/or persistently high natriuretic peptides, end-organ dysfunction (renal or liver), very low left ventricular ejection fraction (< 20%), recurrent defibrillator shocks, > 1 hospitalization in the last 12 months, persistent fluid overload and/or increasing requirement of diuretic use, consistently low blood pressure (< 90-100 mmHg systolic), and the inability to up-titrate or the need to decrease or cease guideline-directed medical therapy (Peled et al. 2024).

The ISHLT states that multiple prognosis scores have been developed to stratify risk in HF patients, such as the Seattle Heart Failure Model (SHFM) and the Heart Failure Survival Score (HFSS). Scores that suggest an estimated 1-year survival of < 85% may help guide decision making, especially in situations where there is ambiguity regarding listing based on other data. However, the values of these scores should not be used as the sole criteria for listing (Peled et al. 2024).

The ISHLT guidelines also discuss heart transplant eligibility in special populations. The authors discuss how cardiac amyloidosis can result in restrictive cardiomyopathy due to the extracellular deposition of proteins in the myocardium, and that clinical recognition and diagnosis of cardiac amyloidosis at its early stage is critical. For carefully selected patients with advanced symptoms and limited extracardiac involvement, heart transplant may improve both quality of life and survival. However, in situations where there is significant extracardiac involvement (e.g., hepatic infiltration, gastrointestinal involvement with malnutrition, pulmonary amyloidosis with refractory effusions, etc.) heart transplant is not recommended (Peled et al. 2024).

When considering contraindications, the ISHLT recommends, in general, to consider whether the extracardiac condition will contribute to mortality risk to the point that the expected improvement in survival from transplantation is not received. Additionally, one should consider whether the contraindication will impact post-transplant quality of life and impair rehabilitation efforts, and whether the condition will worsen with immunosuppression. For patients with advanced HF, the authors recommend considering all as potential heart transplant candidates and to prioritize guideline-directed health care maintenance, including control of comorbidities, age-appropriate cancer screening, and vaccinations (Peled et al. 2024).

The **American College of Cardiology (ACC)**, **American Heart Association (AHA)**, and **Heart Failure Society of America (HFSA)** published the *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*, which provides clinical recommendations to prevent, diagnose, and manage patients with HF. The authors note that some patients with chronic HF will continue to progress despite maximum guideline-directed medical therapy, which is described as "advanced," "refractory," or "end-stage" HF. In 2018, the European Society of Cardiology (ESC) updated its definition of advanced HF to focus closer on refractory symptoms rather than cardiac function alone. This update acknowledges that advanced HF can occur in patients without severely reduced ejection fraction, such as those with preserved ejection fraction, isolated right ventricular dysfunction, and uncorrectable CHD or valvular heart disease. The ESC defines advanced HF as follows and emphasizes that all must be present despite optimal guideline-directed treatment (Heidenreich et al. 2022):

- Severe and persistent symptoms of HF (e.g., NYHA class III or IV)
- Severe cardiac dysfunction, defined by at least one of the following:
    - Left ventricular ejection fraction of $\leq$ 30%
    - Isolated right ventricular failure
    - Non-operable severe valve abnormalities
    - Non-operable severe CHD
    - Ejection fraction $\geq$ 40% with elevated natriuretic peptide levels and evidence of significant diastolic dysfunction
- Hospitalizations or unplanned visits in the past 12 months for episodes of any of the following:
    - Malignant arrhythmias
    - Low cardiac output that requires inotropic or vasoactive medication
    - Congestion that requires high-dose intravenous or combination diuretics
- Inability or severe impairment in exercise capacity, with 6-minute walk test (< 300m) or peak VO_2 (< 12-14mL/kg/min), estimated to be of cardiac origin

According to the ACC, AHA, and HFSA, cardiac transplantation provides a quality of life, morbidity, and mortality benefit to select patients with advanced, refractory HF (stage D), with supporting evidence coming from observational cohort studies. Additionally, data from the ISHLT and United Network of Organ Sharing (UNOS) lists the median survival of adult heart transplant recipients to be now > 12 years. Comparatively, the median survival of patients with stage D HF without advanced therapy is < 2 years, and risk of death becomes greater than survival between years 3 and 4 when on a left ventricular assist device, regardless of implant strategy. Minimizing waitlist mortality and maximizing post-transplant outcomes continues to be a priority in heart transplantation. The authors emphasized that "the listing criteria, evaluation, and management of patients undergoing cardiac transplantation are described by the ISHLT" (Heidenreich et al. 2022).

The **ACC** and **AHA** also published the *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*, which lays our performance measures for HF that are appropriate for public reporting or pay-for-performance programs. However, for all measures, patients after heart transplantation or left ventricular assist device placement are excluded (Kittleson et al. 2024).

The **American Association for Thoracic Surgery/International Society for Heart and Lung Transplantation** guidelines (Kirklin et al. 2020) note for patients with advanced biventricular failure who are transplant candidates can be considered for biventricular support or TAH. Patients who received an LVAD as bridge to transplant and remain with poorly controlled right ventricular failure (with or without a temporary right VAD) should be considered for longer-term biventricular support or TAH before end-organ dysfunction ensues.

SUPPLEMENTAL INFORMATION

Stages of Heart Failure

The American Heart Association (AHA) and American College of Cardiology (ACC) define four stages of heart failure (AHA 2025):

- Stage A (at risk for heart failure): Patient is at risk for heart failure but does not yet have symptoms or structural/functional heart disease. Risk factors include high blood pressure, coronary artery disease, diabetes, obesity, exposure to cardiotoxic agents, genetic variants for cardiomyopathy, and family history of cardiomyopathy.
- Stage B (pre-heart failure): Patient is without current or previous symptoms of heart failure but has one or more of the following: structural heart disease, increased filling pressures, or other risk factors.
- Stage C (symptomatic heart failure): Patient has current or previous symptoms of heart failure.
- Stage D (advanced heart failure): Patient has heart failure symptoms that disrupt daily life functions or leads to hospitalization.

New York Heart Association (NYHA) Functional Classification

When heart failure is in stage C or D, clinicians can also assign a classification to help measure overall heart function and symptom severity. The most common classification system is the NYHA Functional Classification, outlined as follows (AHA 2025):

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

Heart Failure Prognosis Scores

The Heart Failure Survival Score (HFSS) is a validated model used to stratify risk for patients under evaluation for heart transplantation by using 7 clinical parameters: resting heart rate, mean blood pressure, left ventricular ejection fraction, serum sodium, the presence or absence of ischemic heart disease, the presence or absence intraventricular conduction defect, and peak VO_2 (Goda et al. 2011). Prognosis scores using the HFSS can be categorized as follows (Aaronson et al. 1997; Goda et al. 2011):

- Low risk: $\geq$ 8.10
- Medium risk: 7.20 to 8.09
- High risk: $\leq$ 7.19

In the original validation cohort, these risk categories corresponded to 1-year event-free survival rates of 88% for low risk, 60% for medium risk, and 35% for high risk (Aaronson et al. 1997).

The Seattle Heart Failure Model (SHFM) is a validated model used to stratify risk and provide an estimate of survival using 20 clinical variables: clinical characteristics (age, gender, weight, NYHA class, ischemic etiology, systolic blood pressure, left ventricular ejection fraction), labs (total cholesterol, hemoglobin, uric acid, serum sodium, lymphocytes), device therapy (implantable cardioverter-defibrillator, resynchronization therapy), and medications (angiotensin-converting enzyme inhibitors, angiotensin receptor blockers, beta blockers, aldosterone blockers, statins, loop diuretic equivalent dose, allopurinol) (Goda et al. 2011; Levy et al. 2006).

Unlike the HFSS, the SHFM isn't a point-based score but instead provides a continuous prediction of survival, originally validated to estimate 1-, 2-, and 3-year survival (Levy et al. 2006). According to the International Society for Heart and Lung Transplantation (ISHLT), an estimated 1-year survival of < 85% may help guide decision making for patients with chronic heart failure (Peled et al. 2024).

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
33927	Implantation of a total replacement heart system (artificial heart) with recipient cardiectomy
33928	Removal and replacement of total replacement heart system (artificial heart)
33929	Removal of a total replacement heart system (artificial heart) for heart transplantation (list separately in addition to code for primary procedure)
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
L8698	Miscellaneous component, supply, or accessory for use with total artificial heart system

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

12/10/2025	Policy revised. Removed language implying a cut-off point for heart failure prognosis scores and changed the SHFM estimated 1-year survival reference from 80% to 85%. Added peripheral vascular disease and connective tissue disease to relative contraindications. Merged policy with MCP-245 Heart Transplantation with a Total Artificial Heart (TAH). Title changed to "Heart Transplantation and Heart Transplantation with a Total Artificial Heart." IRO peer reviewed on October 30, 2025 by a practicing physician board certified in transplant surgery, vascular surgery, general surgery, and surgical critical care.
12/11/2024	Policy revised. 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	Policy revised**.** 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 revised, 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 revised; 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 revised. 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 revised; updated with new pretransplant criteria; condensed medical evidence section.
09/24/2012	New policy.

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