# Molina Clinical Policy
# Heart Transplantation: Policy No. 116
**Last Approval: 2/8/2023**
**Next Review Due By: February 2024**

## 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 million adults annually in the United States and between 12,000 to 35,000 children under age 19 (CDC, 2023; Singh & Singh, 2022). In 2019, heart failure accounted for 10% of deaths related to cardiovascular disease (CVD) (Tsao et al., 2022). In 2022, of the 42,888 transplants performed in the United States, 4,111 were heart transplants – this was an increase of 7.7% compared to 2021 (OPTN, 2022). The one-year survival rate among heart transplant recipients is approximately 90 percent in North America and approximately 80 percent in other areas of the world (Khush et al., 2021). The median survival is more than 12 years (Khush et al., 2018). The one- and five-year survival rates based on race/ethnicity were 91% and 79% for White heart transplant recipients, 91% and 74% for Black recipients, 90% and 80% for Hispanic recipients, and 91% and 80% for Asian recipients (Tsao et al., 2022).

Among pediatric transplant recipients, the median survival post-transplant ranges from 13 years among adolescent recipients to 22 years for infant transplant recipients. Mortality is highest the year following transplant. Mortality rates have improved; estimated five-year post-transplant survival is 82% for transplants that occurred from 2009 to 2014 (compared to 60% of transplants that took place between 1982 and 1989). In addition, pediatric patients have a three-year post-transplant functional status of 80% – this includes normal activity or minor limitations in strenuous activity. Hospitalizations for organ rejection and/or infection are common and occur in 30-40% of patients within three years post-transplant. (Singh & Singh, 2019).

Advances in immunosuppression and transplantation have improved survival rates in heart transplant recipients. Median survival following heart transplantation is 11 years. While mortality is considerable in the first six months following transplant, it improves to approximately 3.4% after that. 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 (CAV), non-specific graft failure, and malignancies. Approximately 3% of recipients undergo re-transplantation; selection criteria are high for those with graft failure (Pham, 2022).

### Donor Selection

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 (VADs). The United Network for Organ Sharing (UNOS) allocation system was updated from a three-level system to a six-tier system in October 2018. Candidates must meet specific criteria to be registered in the UNOS system. (Mancini, 2023).

## COVERAGE POLICY

**All transplants require prior authorization from the Corporate Transplant Department. Solid organ transplant requests will be reviewed by the Corporate Senior Medical Director or qualified clinical designee. 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.*

### Pre-Transplant Evaluation

**(AMR, 2022; Heidenreich et al., 2022; [1-2] MCG, 2022; McDonagh et al., 2021; Yancy et al., 2020; Yancy et al., 2017; Mehra et al., 2016; Costanzo et al., 2010; CMS, 2008)**

**Please see *MCP-323 Pre-Transplant Evaluation* for additional criteria and information.**

**For Total Artificial Heart Transplantation, see *MCP-245: Heart Transplantation with a Total Artificial Heart*.**

Criteria for transplant evaluation include:

1. History and physical examination; **AND**
2. Psychosocial evaluation and clearance:
   a. No behavioral health disorder by history or psychosocial issues:
      - If history of behavioral health disorder, no severe psychosis or personality disorder;
      - Mood/anxiety disorder must be excluded or treated;
      - Member has understanding of surgical risk and post procedure compliance and follow-up required.

   **AND**
   b. Adequate family and social support.

**AND**

3. EKG; **AND**
4. Chest x-ray; **AND**
5. Cardiac clearance in the presence of any of the following:
   a. Chronic smokers; **OR**
   b. Members > 50 years age; **OR**
   c. Those with a clinical or family history of heart disease or diabetes.

**AND**

6. Pulmonary clearance if evidence of pulmonary artery hypertension (PAH) or chronic pulmonary disease; **AND**
7. Neurological exam and clearance for transplant including **ONE** of the following:
   a. Normal exam by H&P; **OR**
   b. Abnormal neurological exam with positive findings including **ONE** of the following:
      - Lumbar puncture normal cytology; **OR**
      - Lumbar puncture with cytological exam abnormal: CNS disease treated prior to clearance.

**AND**

8. A Performance Status that includes **ONE** of the following:
   a. Karnofsky score 70-100%; **OR**
   b. Eastern Cooperative Oncology Group (ECOG) Grade 0-2.

**AND**

9. Lab studies that include:
    a. Complete blood count; kidney profile (blood urea nitrogen, creatinine); electrolytes; calcium; phosphorous; albumin; liver function tests; and coagulation profile (prothrombin time, and partial thromboplastin time);*
    b. Serologic screening for: HIV; Epstein Barr virus (EBV); Hepatitis virus B (HBV); Hepatitis C (HCV); cytomegalovirus (CMV); RPR and/or FTA:*
        - If HIV positive **ALL** of the following must be met:
            i. CD4 count >200 cells/mm-3 for >6 months; **AND**
            ii. HIV-1 RNA undetectable; **AND**
            iii. On stable anti-retroviral therapy >3 months; **AND**
            iv. No other complications from AIDS (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidioides mycosis, resistant fungal infections, Kaposi's sarcoma, or other neoplasm).
        - If abnormal serology, need physician plan to address and/or treatment as indicated.
            i. Antinuclear antibody, smooth muscle antibody, antimitochondrial antibody
            ii. Ceruloplasmin, α1-antitrypsin phenotype
            iii. Alpha-fetoprotein
    c. Urine drug screen (UDS) if Member is current or gives a history of past drug abuse.

**AND**

10. Colonoscopy (if indicated or if Member is age ≥ 50) with complete workup and treatment of abnormal results as indicated; an initial screening colonoscopy after initial negative screening requires a follow-up colonoscopy every 10 years).*

**AND**

11. Gynecological examination with Pap smear for women ages ≥ 21 to ≤ 65 years of age or if indicated (not indicated in women who have had a total abdominal hysterectomy [TAH] or a total vaginal hysterectomy [TVH]) within the last three years with complete workup and treatment of abnormal results as indicated.*

Within the last 12 months:

1. Dental examination or oral exam showing good dentition and oral care or no abnormality on panorex or plan for treatment of problems pre- or post-transplant; **AND**
2. Mammogram (if indicated or > age 40) with complete workup and treatment of abnormal results as indicated;* **AND**
3. PSA if history of prostate cancer or previously elevated PSA with complete workup and treatment of abnormal results as indicated.*

* Participating Centers of Excellence may waive these criteria.

## Adult Criteria for Transplantation

Heart Organ transplantation from a deceased donor **is considered medically necessary** in adult members who are > age 18 years and have met **ALL** of the following criteria:

1. All pre-transplant criteria are met; **AND**

**AND**

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 [SHFM] of < 80% or a Heart Failure Survival Score [HFSS] in the high/medium risk range); **AND**

3. Have **ONE** of the following indications for cardiac transplantation (Mehra et al., 2016; [1] MCG, 2021):

   a. Transplant need, as indicated by at least **ONE** of the following:

   - Cardiogenic shock^ or severe heart failure (New York Heart Association [NYHA] Class IV)** that requires continuous intravenous inotropic support or mechanical cardiac support (such as intra-aortic balloon pump).
     - 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 mm Hg).

   **OR**

   - Severe chronic heart failure as indicated by **ALL** of the following:
     - NYHA Class III or IV (despite maximal medical therapy); **AND**
     - Peak metabolic oxygen consumption on cardiopulmonary exercise test less than 14 mL/kg/min or less than 12 mL/kg/min if patient on beta-blocker.

   **OR**

   - Member has severe cardiac ischemia (angina) despite maximal feasible therapy (revascularization, medication) and consistently limits routine activity that is not amenable to coronary artery bypass surgery or angioplasty; **OR**

   - Recurrent symptomatic or life-threatening ventricular arrhythmia is unresponsive to therapy and interventional procedures such as intracardiac defibrillator, catheter ablation.

   - Reduced exercise capacity (VO2 max < 10 ml/kg/min); **OR**

   - Documented dependence on IV inotropic support to maintain adequate organ perfusion.

   ** NYHA Functional Classification (AHA, 2017):
   I No limitation of physical activity; ordinary physical activity does not cause undue fatigue, palpitation, dyspnea (shortness of breath).
   II Slight limitation of physical activity; comfortable at rest; ordinary physical activity results in fatigue, palpitation, dyspnea.
   III Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, or dyspnea.
   IV Unable to carry on physical activity without discomfort; symptoms of heart failure at rest; discomfort increases with physical activity.

   ^ Defined as decreased cardiac output and evidence of tissue hypoxia in the presence of adequate intravascular volume despite maximum medical therapy.

   **OR**

   b. Severe congenital heart disease as indicated by at least **ONE** of the following:
   - Severe symptomatic cyanotic heart disease not amenable to palliation; **OR**
   - Single ventricle physiology; **OR**
   - Failed Fontan circulation including post-Fontan procedure with refractory heart failure, persistent protein-losing enteropathy, and/or plastic bronchitis despite optimal medical and surgical therapy; **OR**
   - Eisenmenger syndrome; **OR**
   - Reactive pulmonary hypertension with risk for progression to a level of fixed pulmonary vascular resistance that may preclude future transplant; **OR**
   - Ventricular failure due to complex congenital heart disease that is not amenable to other surgical alternatives; **OR**
   - Severe oxygen desaturations not amenable to other surgical correction; **OR**
   - Severe heart failure refractory to medical therapy not amenable to other surgical, interventional, or electrophysiologic intervention.

   **OR**

c. Low-grade myocardial tumor and **ALL** of the following:
   - No evidence of metastatic disease; **AND**
   - Tumor is then unresectable.

**OR**

d. Selected patients with restrictive and hypertrophic cardiomyopathies including cardiac amyloidosis; **OR**

e. Unresectable ventricular diverticula; **OR**

f. Re-transplant is requested for graft dysfunction due to severe allograft vasculopathy.

**AND**

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

**AND**

5. The requesting transplant recipient should not have any of the following <u>absolute contraindications</u>:
   a. Cardiac, pulmonary, and nervous system disease that cannot be corrected and is a prohibitive risk for surgery; **OR**
   b. Malignant neoplasm with a high risk for reoccurrence, non-curable malignancy (excluding localized skin cancer); **OR**
   c. Systemic and/or uncontrolled infection; **OR**
   d. AIDS (CD4 count < 200cells/mm3); **OR**
   e. Unwilling or unable to follow post-transplant regimen:
      - Documented history of non-compliance
      - Inability to follow through with medication adherence or office follow-up

   **OR**
   f. Chronic illness with one year or less life expectancy; **OR**
   g. Limited, irreversible rehabilitation potential; **OR**
   h. Active untreated substance abuse issues, requires documentation supporting free from addiction for minimally 6 months if previous addiction was present; **OR**
   i. No adequate social/family support.

**AND**

6. The requesting transplant recipient should be evaluated carefully and potentially treated if any of the <u>relative contraindications</u> below are present.
   a. Irreversible lung disease patients require consultation and clearance by a Pulmonologist prior to consideration of transplantation including:
      - Pulmonary hypertension that is fixed as evidenced by either:
        i. Pulmonary vascular resistance (PVR) greater than 5 Wood units; **OR**
        ii. Trans-pulmonary gradient (TPG) greater than or equal to 16 mm/Hg.

      **AND**
      - Smoking, documentation supporting free from smoking for 6 months <u>or</u> meets transplant center criteria.

**OR**

b. Active peptic ulcer disease; **OR**
c. Active gastroesophageal reflux disease; **OR**
d. CVA with long term impairment that is not amendable to rehabilitation or a patient with CVA/transient ischemic attack within past 6 months; **OR**
e. Pre-transplant body mass index (BMI) < 35 kg/m2 to improve transplant outcomes; **AND**
f. Chronic liver disease such as Hepatitis B/C/D, or cirrhosis which increases the risk of death from sepsis and hepatic failure requires consultation by a gastroenterologist or hepatologist; **OR**
g. Gall bladder disease requires ultrasound of the gall bladder with treatment prior to transplantation; **OR**
h. Multisystem disease with severe extracardiac organ dysfunction.

**Pediatric Criteria for Transplantation**

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

1. End stage 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.

2. Have **ONE** of the following indications for cardiac transplantation (Canter et al., 2007; [2] MCG, 2021):

   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); **OR**

   b. Stage C heart failure (with present or past history of symptomatic heart failure) and **ONE** or more of the following:
      - Maximal oxygen consumption on cardiopulmonary exercise testing (less than 50% of expected level for age/sex); **OR**
      - Heart-disease related growth failure; **OR**
      - Recurrent symptomatic or life-threatening arrhythmia unresponsive to medical therapy and interventional procedures (e.g., catheter ablation, intracardiac defibrillator); **OR**
      - Severe exercise or activity intolerance; **OR**
      - 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; **OR**

   d. Stage C heart failure in pediatric restrictive cardiomyopathy disease associated with reactive pulmonary hypertension; **OR**

   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; **OR**

   **OR**

   f. Severe congenital heart disease with at least **ONE** of the following:

      - Hypoplastic left heart syndrome and 1 or more of the following:
        - Proximal coronary artery stenosis or atresia; **OR**
        - Atrioventricular or semilunar valve with moderate to severe stenosis or insufficiency; **OR**
        - 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; **OR**

- Severe arterial oxygen desaturations (cyanosis) not amenable to other surgical correction; **OR**
- Fontan circulation with systemic complications with at least **ONE** of the following:
  - Protein losing enteropathy; **OR**
  - Plastic bronchitis; **OR**
  - Stroke or thromboembolic disease; **OR**
  - Refractory ascites; **OR**
  - Cirrhosis of the liver; **OR**
- Failed surgical palliation.

**OR**

g. Low-grade myocardial tumor and **ALL** of the following:
- No evidence of metastatic disease; **AND**
- Tumor is then unresectable.

**OR**

h. Re-transplant is requested for graft dysfunction due to severe allograft vasculopathy.

**AND**

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

**AND**

4. The requesting transplant recipient should not have any of the absolute or relative contraindications as outlined above in the Adult Criteria.

**Re-Transplantation**

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

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

**Heart and Lung Transplantation**

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

**For Members with Significant or Daily Cannabis Use**

1. Documentation of compliance with a physician prescribed and managed program of abstinence, and a reasonable expectation that the Member will be abstinent from cannabis use during the transplant and immediate post-transplant time-period. Daily cannabis use is an absolute contraindication for both transplant and pre-transplant evaluation unless there is a state mandate applicable for medical cannabis use and transplants, and there is documentation of Member compliance with a physician prescribed plan of care for prescribed cannabis use.
2. If the Member's cannabis use is in compliance with a formal, State-based program for managed medical cannabis, the request should include:

- Documentation of the Plan of Care for medical cannabis (including the medical decision making that supports the use of medical cannabis); **AND**
- Transplant Provider agreement with the Plan of Care (including agreement to be accountable for managing the Member's use of medical cannabis).

**Continuation of Therapy**

When extension of a previously approved transplant authorization is requested, review using updated clinical information is appropriate.

1. If Molina Healthcare has authorized prior requests for transplantation **ALL** of the following information is required for medical review:
   a. Presence of no absolute contraindication as listed above; **AND**
   b. History and physical within the last 12 months; **AND**
   c. Kidney profile within the last 12 months; **AND**
   d. Cardiac update if history of cardiac disease within two years (≥ 50 years of age); **AND**
   e. Psychosocial evaluation or update within the last 12 months; **AND**
   f. Per initial and updated history and physical, any other clinically indicated tests and/or scans as determined by transplant center physician or Molina Medical Director.

2. If authorized prior requests for transplantation were obtained from another insurer, **ALL** of the following information is required for medical review:
   a. Authorization letter/documentation from previous insurer; **AND**
   b. Presence of no absolute contraindication as listed above; **AND**
   c. History and physical within the last 12 months; **AND**
   d. Cardiac update if history of cardiac disease within two years (≥ 50 years of age); **AND**
   e. Psychosocial evaluation or update within the last 12 months; **AND**
   f. Per initial and updated history and physical, any other clinically indicated tests and/or scans as determined by transplant center physician or Molina Medical Director.

**Limitations and Exclusions**

Heart and Heart-Lung Transplantation is considered not medically necessary when the above criteria are not met. This includes, but is not limited to, the following contraindications (Ahmed & Jain, 2022):

- 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).
- Chronic liver disease or cirrhosis
- Advanced kidney disease (glomerular filtration rate of less than 30 ml/min/1.73m^2)
- Recent stroke or symptomatic, untreated peripheral vascular disease
- Uncontrolled diabetes mellitus with end-organ damage
- Active malignancy (discussion should involve oncologists in shared decision-making regarding transplant)
- Severe lung disease with a forced expiratory volume (FEV1) and forced vital capacity (FVC) less than 50% predicted or evidence of parenchymal lung disease
- Recent pulmonary embolism requiring anticoagulation (within the last 3-6 months)
- Severe pulmonary hypertension (PH) with pulmonary artery systolic pressure greater than 60 mmHg and pulmonary vascular resistance greater than five (5) Wood units (if PH is refractory to medical therapy, then it is an absolute contraindication to heart transplant).
- Psychosocial factors (e.g., lack of social support, disabling psychiatric illness, non-compliance with previous medical management, active smoking or drug use and unwillingness to quit)
- Morbid obesity (body mass index greater than 35 kg/m^2)
- Multisystem disease requiring other transplant procedures (like renal, hepatic, or lung transplant)

**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

The published medical evidence and outcomes for heart and heart-lung transplantation in children and adults in the United States consists of registry data obtained from transplant centers that perform adult and pediatric transplantation. This registry is available from the United Network for Organ Sharing (UNOS) database. Registry data demonstrates graft survival rates and outcomes comparable to other organ transplants.

**Pediatric Heart Transplant**

Certain anatomic and physiological conditions likely to worsen the natural history of CHD in infant patients with a functional single ventricle, which can lead to use of heart transplantation as primary therapy, including: (i) severe stenosis (stenoses) or atresia in proximal coronary arteries; (ii) moderate to severe stenosis and/or insufficiency of the AV and/or systemic semilunar valve(s); and (iii) severe ventricular dysfunction. Several anatomic and physiological conditions likely to worsen the natural history of previously repaired or palliated CHD in pediatric patients with stage C heart failure that may lead to consideration for heart transplantation without severe systemic ventricular dysfunction, including (i) pulmonary hypertension and a potential risk of developing fixed, irreversible elevation of pulmonary vascular resistance that could preclude orthotopic heart transplantation in the future; (ii) severe aortic or systemic AV valve insufficiency that is not considered amenable to surgical correction; (iii) severe arterial oxygen desaturation (cyanosis) that is not considered amenable to surgical correction; and (iv) persistent protein-losing enteropathy despite optimal medical/surgical therapy. (Canter et al., 2007).

**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 update requirements; adult and pediatric status exceptions; waiting time; and heart allocation classifications and rankings (OPTN, 2023).

The **International Society for Heart Lung Transplantation (ISHLT)** published *Guidelines for the Care of Heart Transplant Candidates* (Costanzo et al., 2010). The ISHLT has not updated the guidelines since original publication. Section one covers peri-operative care recipients (including surgical issues during early post-operative care); monitoring and treatment of early hemodynamic, metabolic, and infectious issues; evaluation and treatment of allosensitization; evaluation and treatment of early coagulopathies; organization of a multidisciplinary care team; management of ABO (incompatible blood type) in pediatric patients; and the use of extracorporeal membrane oxygenation (ECMO) for the hemodynamic support of pediatric recipients.

Section two covers the mechanisms, diagnosis, and treatment of heart transplant rejection; action, dosing, and drug level monitoring of immunosuppressive drugs (including adverse effects and interactions with concomitantly used medications); and a review of major clinical trials and immunosuppressive strategies for special clinical situations. Section three focuses on clinical issues occurring long-term following transplantation. This includes cardiac allograft vasculopathy, chronic adverse effects of immunosuppression (such as neurotoxicity, renal insufficiency, hypertension, bone disease, diabetes and malignancy), as well as reproductive health, exercise, psychologic problems, return to work, and operation of motor vehicles after heart transplantation. (Costanzo et al., 2010).

In addition, the **ISHLT** published the *2016 International Society for Heart Lung Transplantation Listing Criteria for Heart Transplantation: A 10-Year Update* (Mehra et al., 2016). The updated guideline, originally published in 2006, focuses on evolving areas that were previously not addressed adequately. Topics include congenital heart disease (CHD), restrictive cardiomyopathy, and infectious diseases. Criteria are categorized by section:

- **Section I (General Considerations): A Review and Revision of the 2006 Guideline.** Covers recommendations for:
  - Cardiopulmonary stress testing
  - Use of heart failure survival prognosis scores
  - Role of diagnostic right-heart catheterization
  - Comorbidities and their implications for transplant listing (including age, obesity, diabetes mellitus, renal function, cerebral and peripheral vascular disease, assessment of frailty, mechanical circulatory support [MCS] for bridge to candidacy)

- Tobacco use, substance abuse, and psychosocial evaluation in candidate
- Guidance for screening grids and serial pre-transplant evaluation
- Dynamic listing and new donor allocation algorithms
- Re-transplantation

- **Section II (Special Considerations): Restrictive and Infiltrative Cardiomyopathy**
  - Restrictive cardiomyopathies
  - Cardiac amyloidosis
  - Hypertrophic cardiomyopathy and arrhythmogenic right ventricular dysplasia
- **Section III (Special Considerations): Infectious Diseases.** Includes recommendations related to heart transplantation and patients with any of the following conditions: HIV/AIDS, Chagas disease, Tuberculosis, Hepatitis B and C, as well as vaccine-preventable infections.
- **Section IV (Special Considerations): CHD.** A large number of heart transplant candidates are children with CHD and adult survivors of CHD. This section focuses on issues specific to these populations including sensitization and reasons to require transplantation in the absence of overt heart failure. For example, failing Fontan circulation which makes it difficult to bridge such candidates to a timely, successful transplantation.

To see the full recommendations, the 2016 updated ISHLT guideline is available here.

The **European Society of Cardiology (ESC)** (2021) updated their 2016 guidelines in 2021. For the full list of recommendations published by the ESC can be found here. New concepts include:

a. The term 'heart failure with mid-range ejection fraction' was changed to 'heart failure with mildly reduced ejection fraction' (HFmrEF).
b. A new simplified treatment algorithm for HFrEF (includes addition of algorithm for HFrEF by phenotypes).
c. Modified classification for acute heart failure.
d. Updated treatments for most non-cardiovascular comorbidities including diabetes, hyperkalaemia, iron deficiency, and cancer.
e. Cardiomyopathies and the role of genetic testing and new treatments.
f. Key quality indicators.

The **American College of Cardiology (ACC) and American Heart Association (AHA)** published the updated *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). In addition, the following have also been published (see Reference section for links):

- *2021 ACC/AHA Key Data Elements and Definitions for Heart Failure* (Bozkurt et al., 2021)
- *2020 ACC/HFSA/ISHLT Lifelong Learning Statement for Advanced Heart Failure and Transplant Cardiology Specialists* (Yancy et al., 2020)
- *2020 ACC/AHA Clinical Performance and Quality Measures for Adults with Heart Failure* (Heidenreich, 2020)

## SUPPLEMENTAL INFORMATION

None.

## 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 is able to provide the specialized facilities, services, and personnel that are required by pediatric heart transplant patients.

### CPT Codes

| CPT | 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 Code

| HCPCS | 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

| | |
|---|---|
| **2/8/2023** | Policy reviewed, no changes to criteria, included section on cannabis use. |
| **2/9/2022** | Policy reviewed; updated items from 2016 ISHLT criteria; included marijuana use under absolute contraindications; updated Summary of Medical Evidence and Reference sections. |
| **9/18/2019, 4/23/2020, 2/8/2021** | Policy reviewed, no changes, updated references. |
| **9/13/2018** | 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. |
| **9/15/2016, 6/22/2017** | No changes to criteria. |
| **4/9/2015** | Policy reviewed; updated with new pretransplant criteria; condensed medical evidence section. |
| **9/24/2012** | New policy. |

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