

| | | |
|--|--|--|
| Subject: Heart Transplantation | | Original Effective Date: 9/24/12 |
| Policy Number: MCP-116 | Revision Date(s): 4/8/15, 9/13/18 | |
| Review Date: 12/16/15, 9/15/16, 6/22/17, 9/18/19, 4/23/20, 2/8/21 | | |
| MCPC Approval Date: 9/13/18, 9/18/19, 4/23/20, 2/8/21 | | |

Contents

| | |
|--|----|
| DISCLAIMER | 1 |
| DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL | 1 |
| POSITION STATEMENT CRITERIA | 2 |
| Continuation of Therapy | 7 |
| Limitations | 8 |
| Summary of Medical Evidence | 8 |
| Coding Information | 8 |
| Resource References | 9 |
| CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS) | 11 |
| Review/Revision History | 11 |

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. 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 (i.e., 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 Molina Clinical Policy (MCP) document and provide the directive for all Medicare members.¹

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL

Heart transplantation is a procedure where the failing damaged heart is replaced with another heart from a suitable cadaver donor. It is generally reserved in adult patients who have end-stage congestive heart failure with less than 1 year to live without the transplant and who are refractory to conventional medical and surgical

therapy. Heart transplantation is performed in infants and children who have end-stage cardiomyopathy who are refractory to medical therapy, in patients with previously repaired or palliated congenital heart disease who have developed ventricular dysfunction or other non-operable late-term complications, and in patients with complex congenital heart disease where standard surgical procedures are extremely high risk. Candidacy determination and evaluation are key components of the process, as are postoperative follow-up care and immunosuppression management. Candidates for cardiac transplantation generally present with New York Heart Association (NYHA) functional class III (moderate) symptoms or class IV (severe) symptoms. The Cardiopulmonary evaluation usually demonstrates ejection fractions of less than 25%. Attempts are made to stabilize the cardiac condition while the evaluation process is undertaken and can include oral agents as well as inotropic support. Mechanical support with the intra-aortic balloon pump (IABP) or implantable assist devices may be appropriate in some patients as a bridge to transplantation.

A heart-lung transplant is a procedure where the transplantation of one or both lungs and heart from a single cadaver donor is done. A combined heart-lung transplant is intended to prolong survival and improve function in recipients with end stage cardiopulmonary disease. The surgical technique requires a coordinated triple operative procedure that includes the procurement of a donor heart-lung block, surgical removal of the heart and lungs of a single cadaver donor, and implantation of the heart and lungs into the recipient.

After transplantation, endomyocardial biopsies are performed to assess for allograft rejection. These may be performed as frequently as every week for the first month, with the frequency decreasing over time. Follow-up visits are frequent for the first month because regulation of immunosuppression is being adjusted during this time. The frequency of visits gradually diminishes until the patient is generally seen on an annual basis. Coronary angiography may be performed annually after transplantation to monitor the patient for the development of allograft vascular disease depending upon each centers requirements.

POSITION STATEMENT CRITERIA ^{1 4-8 20-24}

All transplants require prior authorization from the Corporate Transplant Department. Solid organ transplant requests will be reviewed by the Medical Director or qualified clinical designee. All other transplants will be by the Corporate 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 Medical Director's designee can approve the requested transplant.

Members must meet the Organ Procurement & Transplantation Network (OPTN)/United Network Organ Sharing (UNOS) guidelines for pretransplantation evaluation and listing criteria and the diagnosis must be made by a *Specialist in the Disease* and or Transplant Surgeon.

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

Criteria for transplant evaluation include all of the following:

- ☐ History and physical examination: includes a complete evaluation that meets the transplant center's protocol eligibility criteria

- ☐ Psychosocial evaluation and clearance:
 - 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
 - Adequate family and social support
- ☐ EKG
- ☐ Chest x-ray
- ☐ Cardiac clearance in the presence of any of the following:
 - chronic smokers
 - > 50 years age
 - those with a clinical or family history of heart disease or diabetes
- ☐ Pulmonary clearance if evidence of pulmonary artery hypertension (PAH) or chronic pulmonary disease
- ☐ Lab studies:
 - *Complete blood count, Kidney profile (blood urea nitrogen, creatinine), electrolytes, calcium, phosphorous, albumin, liver function tests, Coagulation profile (prothrombin time, and partial thromboplastin time)
 - *Serologic screening for HIV, Epstein Barr virus (EBV), Hepatitis virus B (HBV), and Hepatitis C(HCV), cytomegalovirus (CMV), RPR and/or FTA:
 - If HIV positive all of the following are met:
 - CD4 count >200 cells/mm-3 for >6 months
 - HIV-1 RNA undetectable
 - On stable anti-retroviral therapy >3 months
 - 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
 - UDS (urine drug screen) if patient is current or gives a history of past drug abuse
- ☐ *Colonoscopy (if indicated or if patient is 50 ≥ older should have had an initial screening colonoscopy, after initial negative screening requires follow up colonoscopy every ten years) with complete workup and treatment of abnormal results as indicated
- ☐ *GYN examination with Pap smear for women ≥ 21 to ≤ 65 years of age or indicated (not indicated in women who have had a TAH or TVH) with in the last three year with complete workup and treatment of abnormal results as indicated

Within the last 12 months:

- ☐ 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
- ☐ *Mammogram (if indicated or > age 40) with complete workup and treatment of abnormal results as indicated
- ☐ *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:

1. 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: [ALL]

- ☐ All pre-transplant criteria are met; and
 - Documentation that all medical, pharmaceutical and surgical alternatives to transplant have been utilized if applicable that includes but is not limited to the following:
 - alcohol septal ablation, myomectomy, mitral valve replacement, maximal medical therapy or pacemaker therapy in patients with cardiomyopathy
 - failed previous surgical correction or condition is not amendable to surgery in patients with congenital heart disease
 - percutaneous coronary intervention or not amenable to coronary artery bypass surgery in patients with coronary artery disease
 - valve replacement or repair in patients with valvular disease
 - low sodium diet, diuretics, fluid restriction for patients with congestive heart failure
 - pacing cardioverter defibrillator, electrophysiology guided single- or combination medical therapy, or not a candidate for ablative therapy in patients with arrhythmias
 - coronary artery bypass surgery or percutaneous coronary intervention in patients with severe angina; *and*
- ☐ NY Class IV* with life expectancy without transplant 6-12 months; *and*
 - Severe ischemia consistently limiting routine activity not amenable to coronary artery bypass surgery or angioplasty, *or*
 - Recurrent symptomatic ventricular arrhythmias refractory to **ALL** accepted therapeutic modalities; *or*
 - Selected patients with restrictive and hypertrophic cardiomyopathies including cardiac amyloidosis; or
 - Congenital heart disease with any of the following:
 - Severe symptomatic cyanotic heart disease not amenable to palliation; or
 - Post-Fontan procedure with refractory HF, persistent protein-losing enteropathy, and/or plastic bronchitis despite optimal medical and surgical therapy; or
 - Pulmonary hypertension with the potential risk of developing fixed, irreversible elevation of pulmonary vascular resistance (PVR) that could preclude heart transplantation in the future; or
 - End stage, irreversible, refractory, symptomatic heart failure despite optimal medical therapy and any of the following: [ONE]
 - Refractory Cardiogenic shock: defined as decreased cardiac output and evidence of tissue hypoxia in the presence of adequate intravascular volume despite maximum medical therapy. Criteria include: sustained hypotension (systolic blood pressure < 90 mm Hg for at least 30 min) and a reduced cardiac index (< 2.2 L/min/m²) in the presence of elevated pulmonary capillary wedge pressure (>15 mm Hg); or
 - Reduced exercise capacity (VO₂ max < 10 ml/kg/min); or
 - Documented dependence on IV inotropic support to maintain adequate organ perfusion

AND

The requesting transplant recipient should not have any of the following **absolute contraindications**:

- ☐ Cardiac, pulmonary, and nervous system disease that cannot be corrected and is a prohibitive risk for surgery
- ☐ Malignant neoplasm with a high risk for reoccurrence, non-curable malignancy (excluding localized skin cancer)
- ☐ Systemic and/or uncontrolled infection
- ☐ AIDS (CD4 count < 200cells/mm³)
- ☐ Unwilling or unable to follow post-transplant regimen
 - Documented history of non-compliance
 - Inability to follow through with medication adherence or office follow-up
- ☐ Chronic illness not reversible with heart transplant with one year or less life expectancy
- ☐ Limited, irreversible rehabilitation potential
- ☐ Active untreated substance abuse issues, requires documentation supporting free from addiction for minimally 6 months if previous addiction was present
- ☐ No adequate social/family support

The requesting transplant recipient should be evaluated carefully and potentially treated if the following **relative contraindications** are present:

- ☐ Irreversible lung disease patients require consultation and clearance by a Pulmonologist prior to consideration of transplantation, this includes the following:
 - Pulmonary hypertension that is fixed as evidenced by either:
 - Pulmonary vascular resistance (PVR) greater than 5 Wood units; or
 - Trans-pulmonary gradient (TPG) greater than or equal to 16 mm/Hg; and
 - Smoking, documentation supporting free from smoking for 6 months OR meets transplant center criteria
- ☐ Active peptic ulcer disease
- ☐ Active gastroesophageal reflux disease
- ☐ CVA with long term impairment that is not amendable to rehabilitation or a patient with CVA/transient ischemic attack within past 6 months
- ☐ Obesity with body mass index of >30 kg/m² may increase surgical risk
- ☐ 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
- ☐ Gall bladder disease requires ultrasound of the gall bladder with treatment prior to transplantation
- ☐ Multisystem disease with severe extracardiac organ dysfunction

Pediatric Criteria for Transplantation:

2. 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: **[ALL]**
 - ☐ Documentation that all medical and surgical alternatives to transplant have been utilized if applicable that includes but is not limited to the following :
 - alcohol septal ablation, myomectomy, mitral valve replacement, maximal medical therapy or pacemaker therapy in patients with cardiomyopathy

- failed previous surgical correction or condition is not amendable to surgery in patients with congenital heart disease
 - percutaneous coronary intervention or not amenable to coronary artery bypass surgery in patients with coronary artery disease
 - valve replacement or repair in patients with valvular disease
 - low sodium diet, diuretics, fluid restriction for patients with congestive heart failure
 - pacing cardioverter defibrillator, electrophysiology guided single- or combination medical therapy, or not a candidate for ablative therapy in patients with arrhythmias
 - coronary artery bypass surgery or percutaneous coronary intervention in patients with severe angina; **and**
- ☐ End stage heart failure with persistent symptoms at rest who require one or more of the following:[ONE]
- Continuous infusion of intravenous inotropic agents, **or**
 - Mechanical ventilatory support, **or**
 - Mechanical circulatory support
- ☐ Pediatric heart disease with symptoms of heart failure who do not meet the above criteria but who have one of the following:[ONE]
- Severe limitation of exercise and activity (if measurable, such patients would have a peak maximum oxygen consumption <50% predicted for age and sex), **or**
 - Cardiomyopathies or previously repaired or palliated congenital heart disease and significant growth failure attributable to the heart disease, **or**
 - Near sudden death and/or life-threatening arrhythmias untreatable with medications or an implantable defibrillator, **or**
 - Restrictive cardiomyopathy with reactive pulmonary hypertension, **or**
 - Reactive pulmonary hypertension and potential risk of developing fixed, irreversible elevation of pulmonary vascular resistance that could preclude orthotopic heart transplantation in the future, **or**
 - Anatomical and physiological conditions likely to worsen the natural history or congenital heart disease in infants with a functional single ventricle, **or**
 - Anatomical and physiological conditions that may lead to consideration for heart transplantation without systemic ventricular dysfunction

AND

The requesting transplant recipient should not have any of the **absolute or relative contraindications outlined above in the adult criteria.**

Retransplantation:

3. 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: [ONE]
 - ☐ graft failure of an initial heart transplant due to either technical reasons or acute rejection; or
 - ☐ chronic rejection; or
 - ☐ significant cardiac allograft vasculopathy with refractory cardiac allograft dysfunction, without evidence of ongoing acute rejection; or
 - ☐ recurrent disease
4. 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.

***NYHA Functional Classification is defined as:**

| | |
|------------|---|
| I | Patients without resulting limitations of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain. |
| II | Patients with a slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea, or anginal pain. |
| III | Patients with marked limitation of physical activity. They are comfortable at rest. Less than ordinary physical activity causes fatigue, palpitation, dyspnea, or anginal pain. |
| IV | Patient with the inability to carry on any physical activity without discomfort. Symptoms of cardiac insufficiency or of the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increased. |

Note: Total Artificial Heart: Please see specific MCP entitled *Heart Transplantation with a Total Artificial Heart* for criteria.

CONTINUATION OF THERAPY

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

- ☐ If Molina Healthcare has authorized prior requests for transplantation, the following information is required for medical review: [ALL]
 - Presence of no absolute contraindication as listed above;
 - History and physical within the last 12 months;
 - Kidney profile within the last 12 months;
 - Cardiac update if history of cardiac disease within two years (≥ 50 years of age);
 - Psychosocial evaluation or update within the last 12 months;
 - 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.

- ☐ If authorized prior requests for transplantation were obtained from another insurer, the following information is required for medical review: [ALL]
- Authorization letter/documentation from previous insurer;
 - Presence of no absolute contraindication as listed above;
 - History and physical within the last 12 months;
 - Cardiac update if history of cardiac disease within two years (≥ 50 years of age);
 - Psychosocial evaluation or update within the last 12 months;
 - 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

Heart and Heart-Lung Transplantation is considered not medically necessary when the above criteria are not met.

SUMMARY OF MEDICAL EVIDENCE ^{2-3 12-22}

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 and is available from the United Network for Organ Sharing (UNOS) database. Registry data demonstrates graft survival rates and outcomes comparable to other organ transplants.

CODING INFORMATION THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

| CPT | Description |
|-------|--|
| 33930 | Donor cardiectomy-pneumectomy (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-pneumectomy |
| 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 | 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 |

| ICD-10 | Description: [For dates of service on or after 10/01/2015] |
|--------|--|
|--------|--|

| | |
|-----------|---|
| I21-I21.4 | Acute myocardial infarction |
| I20.8 | Other forms of angina pectoris |
| I25.10 | Atherosclerotic heart disease of native coronary artery without angina pectoris |
| I20-I25.9 | Ischemic Heart Disease |
| I40.9 | Acute myocarditis, unspecified |
| I42.3 | Endomyocardial (eosinophilic) disease |
| I42.2 | Other hypertrophic cardiomyopathy |
| I42-I42.9 | Cardiomyopathy |
| I49-I49.9 | Cardiac Arrhythmias |
| I50-I50.9 | Heart Failure |
| Q20.0 | Common arterial trunk |
| Q20-Q25.9 | Congenital malformations of the heart |
| R57.0 | Cardiogenic shock |

RESOURCE REFERENCES

Government Agency

- Centers for Medicare & Medicaid Services. NCD for Heart Transplants (260.9). 2008. Accessed at: <http://www.cms.gov/medicare-coverage-database/>
- United States Organ Procurement and Transplantation Network and the Scientific Registry of Transplant Recipients. OPTN/SRTR national data: Heart transplantation. Accessed at: : <http://www.srtr.org/>
- The United States Organ Procurement and Transplantation Network (OPTN) and The United Network for Organ Sharing (UNOS) Policies: Policy 6 Organ Distribution: Allocation of Hearts and Heart-Lungs. Accessed at: <http://optn.transplant.hrsa.gov/>

Professional Society Guidelines

- ACCF/AHA Practice Guideline:
 - Yancy CW, Jessup M, Bozkurt B, et al. 2017 ACC/AHA/HFSA Focused Update Guideline for the Management of Heart Failure. Focused Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure. A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Failure Society of America. Accessed at: http://www.onlinejacc.org/content/70/6/776?_ga=2.39938210.1865471408.1566410944-1684559738.1566410944
 - Yancy CW, et al. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *Circulation* 2013;128(16):e240-319.
 - Jessup M, Abraham W et al. 2009 Focused Update: ACCF/AHA Guidelines for the Diagnosis and Management of Heart Failure in Adults. Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines: *Developed in Collaboration With the International Society for Heart and Lung Transplantation*. Accessed at: <http://circ.ahajournals.org/content/119/14/1977.full>
 - Nishimura RA, et al. 2014 AHA/ACC guideline for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. *Circulation* 2014;129(23):e521-643. DOI: 10.1161/CIR.0000000000000031. (Reaffirmed 2017 Oct)

5. European Society of Cardiology (ESC) 2016 Guidelines for the diagnosis and treatment of acute and chronic heart failure. Eur Heart J 2016;May 20. Accessed at: <http://www.acc.org/latest-in-cardiology/ten-points-to-remember/2016/06/15/12/24/2016-esc-guidelines-for-the-diagnosis-and-treatment-of-hf>
6. International Society for Heart and Lung Transplantation (ISHLT):
 - Listing criteria for heart transplantation: A 10-year update. Journal of Heart and Lung Transplantation. 2016. J Heart Lung Transplant. 2016 Jan;35(1):1-23.
 - Guidelines for the care of cardiac transplant candidates. 2006.
7. Steinman TI, Becker BN, et al.; Clinical Practice Committee, American Society of Transplantation. Guidelines for the referral and management of patients eligible for solid organ transplantation. Transplantation. 2001 May 15;71(9):1189-204.
8. The Heart Failure Society of America 2010 Comprehensive Heart Failure Practice Guideline. Journal of Cardiac Failure 2010;16:e1-e194.

Peer Reviewed Publications

9. Atluri P, Hiesinger W, Gorman RC, Pochettino A, Jessup M, Acker MA, et al. Cardiac retransplantation is an efficacious therapy for primary cardiac allograft failure. J Cardiothorac Surg. 2008 May 7;3:26.
10. Haddad H, Isaac D, Legare JF, Pflugfelder P, Hendry P, Chan M, et al. Canadian Cardiovascular Society Consensus Conference update on cardiac transplantation 2008: Executive Summary. Can J Cardiol. 2009 Apr;25(4):197-205.
11. Kilic A, Weiss ES, Arnaoutakis GJ, et al. Identifying Recipients at High Risk for Graft Failure After Heart Retransplantation. Ann Thorac Surg. 2012 Mar;93(3):712-6
12. Kilic A, Weiss ES, Yuh DD, et al. Factors associated with 5-year survival in older heart transplant recipients. J Thorac Cardiovasc Surg. 2012 Feb;143(2):468-74.
13. Kilic A, Weiss ES, George TJ, et al. What Predicts Long-Term Survival After Heart Transplantation? An Analysis of 9,400 Ten-Year Survivors. Ann Thorac Surg. 2012 Mar;93(3):699-704.
14. Richmond ME, Addonizio LJ, Hsu DT, Mital SR, Mosca RS, Quaeqebour JM. Cardiac retransplantation in high risk pediatric patients. Pediatr Transplant. 2007 Sep;11(6):615-23.
15. Ross M, Kouretas P et al. Ten- and 20-year survivors of pediatric orthotopic heart transplantation. J Heart Lung Transplant. 2006 Mar;25(3):261-70.
16. Roussel JC, Baron O, Perigaud C, Bizouam P, Pattier S, Habash O, et al. Outcome of heart transplants 15 to 20 years ago: graft survival, post-transplant morbidity, and risk factors for mortality. J Heart Lung Transplant. 2008 May;27(5):486-93
17. Singh TP, Blume ED, Alexander PM, Gauvreau K. Association of hemodynamic profiles with wait-list mortality in children listed for heart transplantation with idiopathic dilated cardiomyopathy. Am J Cardiol. 2015 Jan 15;115(2):243-8. doi: 10.1016/j.amjcard.2014.10.030. Epub 2014 Oct 30
18. Weiss ES, Nwakanma LU, Patel ND, Yuh DD. Outcomes in patients older than 60 years of age undergoing orthotopic heart transplantation: an analysis of the UNOS database. J Heart Lung Transplant. 2008 Feb;27(2):184-91.
19. Yoda M, Tenderich Zittermann A, Schulte-Eistrup S, Korfer R, Minami K. Long-term survival after cardiac retransplantation: single-center experience. Int Heart J. 2008 Mar;49(2):213-20.
20. Tabarsi N, et al. Meta-analysis of the effectiveness of heart transplantation in patients with a failing fontan. American Journal of Cardiology 2017;119(8):1269-1274. DOI: 10.1016/j.amjcard.2017.01.001.

Other Resources

21. McKesson InterQual CP Procedures: Transplantation, Cardiac. 2019.
22. MCG Care Guidelines. 24th edition. 2020. Heart Transplant Adult (S-535) & Pediatric ORG: P-535 (ISC).
23. UpToDate. [website]: Waltham, MA: Walters Kluwer Health; 2021

- Colucci WS. Evaluation of the patient with heart failure.
- Singh RK. Etiology and diagnosis of heart failure in infants and children.
- Nador R, Lien D. Heart Lung Transplantation.
- Colucci W. Pina LI. Indications and Contraindications for Cardiac Transplantation.
- Connolly H. Management of Eisenmenger syndrome.

24. Advanced Medical Review (AMR):

- Policy reviewed by practicing MD board certified Internal Medicine, Cardiovascular Disease. September 5, 2012
- Policy reviewed by practicing MD board certified in Internal Medicine, Cardiovascular Disease, Critical Care and also reviewed by MD Board certified in Surgery General, Surgery Transplant. August 6, 2018.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this Molina Clinical Policy (MCP) document and provide the directive for all Medicare members.

CMS has an NCD entitled Heart Transplantation (260.9) and covers the procedure in adults when performed in a facility which is approved by Medicare as meeting institutional coverage criteria.¹

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.

REVIEW/REVISION HISTORY

9/24/12: New Policy

4/9/15: This policy was updated with new pretransplant criteria. The medical evidence section was condensed. There were no changes to the criteria for transplantation.

9/15/16, 6/22/17: No changes to criteria

9/13/18: This policy was updated with changes to criteria according to updated professional society guidelines: Under adult indications for transplant added criteria for restrictive and hypertrophic cardiomyopathies, and congenital heart disease. 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.

9/18/19 & 4/23/20 & 2/8/21: Policy reviewed, no changes. Updated references.