

Clinical Policy: Pediatric Heart Transplant

Reference Number: CP.MP.138

Date of Last Revision: 07/26

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Description

Pediatric heart disease may be a progressive disease, affecting cardiac structure and function in infants and children. Heart transplantation is the treatment of choice for pediatric patients with end-stage heart disease. This policy establishes the medical necessity requirements for pediatric heart transplants and re-transplants.

Policy/Criteria

- I. It is the policy of health plans affiliated with Centene Corporation® that heart transplant for pediatric members/enrollees (age < 18) with end-stage heart disease is **medically necessary** when all of the following conditions are met:
 - A. End-stage heart disease due to any of the following indications¹:
 1. *For heart transplantation, one of the following:*
 - a. Stage D heart failure (see table 1) associated with systemic ventricular dysfunction with cardiomyopathies or previously repaired/palliated congenital heart disease (CHD);
 - b. Stage C heart failure associated with any of the following:
 - i. Severe limitation of exercise and activity, evidenced by peak maximum oxygen consumption < 50% predicted for age and sex;
 - ii. 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;
 - iii. Near sudden death, and/or life-threatening arrhythmias untreatable with medications or an implantable defibrillator;
 - iv. Restrictive cardiomyopathy disease associated with reactive pulmonary hypertension;
 - v. 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;
 - vi. Certain anatomic and physiological conditions likely to worsen the natural history of previously repaired or palliated CHD that may lead to consideration for heart transplantation without severe systemic ventricular dysfunction, including any of the following:
 - a) Pulmonary hypertension and a potential risk of developing fixed, irreversible elevation of pulmonary vascular resistance that could preclude orthotopic heart transplantation in the future;
 - b) Severe aortic or systemic AV valve insufficiency that is not considered amenable to surgical correction;
 - c) Severe arterial oxygen desaturation (cyanosis) that is not considered amenable to surgical correction;

- d) Persistent protein-losing enteropathy despite optimal medical/surgical therapy;
- c. 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 any of the following:
 - i. Severe stenosis (stenoses) or atresia in proximal coronary arteries;
 - ii. Moderate to severe stenosis and/or insufficiency of the atrioventricular (AV) and/or systemic semilunar valve(s);
 - iii. Severe ventricular dysfunction;
- 2. *For heart re-transplantation*, moderate to severe cardiac graft vasculopathy;
- B. Life expectancy in the absence of cardiopulmonary disease ≥ 2 years;
- C. All reversible causes of heart failure have been ruled out such as, but not limited to, anemia, hypertension, renal failure, acidosis, obesity, malnutrition, respiratory disorders and thyroid disorders;
- D. Does not have any of the following contraindications:
 - 1. Glomerular filtration rate < 30 mL/min/1.73m² unless being considered for multi-organ transplant;
 - 2. HIV infection with detectable viral load, unless all of the following are documented:
 - a. CD4 cell count >200 cells/mm³,
 - b. Absence of active AIDS-defining opportunistic infection (unless treated efficaciously or prevented, can be included on the heart transplant waiting list) or malignancy;
 - c. Member/enrollee is currently on effective ART (antiretroviral therapy)¹⁰;
 - 3. Severe, irreversible, fixed elevation of pulmonary vascular resistance;
 - 4. Severe hypoplasia of the central branch pulmonary arteries or pulmonary veins;
 - 5. Any specific congenital heart lesion, except in circumstances noted in I.A.;
 - 6. Retransplantation when performed during an episode of ongoing, acute allograft rejection, even in the presence of graft vasculopathy;
 - 7. Retransplantation when performed during the first six months after primary transplantation;
 - 8. Malignancy with high risk of recurrence or death related to cancer;
 - 9. Advanced liver disease or cirrhosis, unless being considered for multi-organ transplant;
 - 10. Acute renal failure with rising creatinine or on dialysis and low likelihood of recovery;
 - 11. Other severe uncontrolled medical condition expected to limit survival after transplant;
 - 12. Uncorrected atherosclerotic disease with suspected or confirmed end-organ ischemia or dysfunction;
 - 13. Chronic infection with highly virulent and/or resistant microbes that are poorly controlled pre-transplant;
 - 14. Active tuberculosis infection;
 - 15. Progressive, irreversible cognitive impairment unrelated to the disease process of the organ requiring transplantation;
 - 16. Significant chest wall/spinal deformity expected to cause severe restriction after transplantation;

17. Inability to adhere to the regimen necessary to preserve the transplant, even with caregiver support;
18. Active substance use or dependence including current tobacco use, vaping, marijuana use (unless prescribed by a licensed practitioner), or IV drug use without convincing evidence of risk reduction behaviors, such as meaningful and/or long-term participation in therapy for substance abuse and/or dependence (unless urgent transplant timelines are present, in which case a commitment to reducing behaviors is acceptable).

Background

Pediatric heart disease incorporates a wide range of diseases and includes a variety of age ranges. Heart transplantation is recommended for end-stage pediatric heart disease. Cardiomyopathy is the most common indication for heart transplant in children and dilated cardiomyopathy is the most common form of cardiomyopathy in the pediatric population, followed by hypertrophic and restrictive diseases.¹

The American Heart Association has published a scientific statement specifically to address the requirements for heart transplantation and re-transplantations in pediatric heart disease.¹ Canter, *et al*, addresses the indications for heart transplants and defines the staging of heart failure as illustrated in Table 1.

The current survival rates in pediatric recipients one, five, and ten years after transplantation is approximately 90, 80, and 60%, respectively.² The median survival is 22.3 years for infants, 18.4 years for children ages one through five, 14.4 years for children ages six to ten, and 13.1 years for children ages 11 years or older at the time of transplanation.¹⁰ Several risk factors contribute to the decreasing survival in older ages groups, including immature immune system in infants, the absence of preformed antibodies in infants, sensitization in the older children due to surgical repair for congenital heart disease, and medication non-compliance in older children.³

Dipchand, *et al*, analyzed the Registry of the International Society for Heart and Lung Transplantation and reported the proportion of transplant recipients by age accordingly: 24% infants, 25% aged between one to five, 16% aged between six to ten years, and 35% aged between 11 and 17 years.⁵

Table 1: Heart Failure Stages in Pediatric Heart Disease

Classification	Characteristics
A	At high risk for developing heart failure
B	Abnormal cardiac structure and/or function; no symptoms of heart failure
C	Abnormal cardiac structure and/or function; past or present symptoms of heart failure
D	Abnormal structure and/or function; continuous infusion of intravenous inotropes or prostaglandin E ₁ to maintain patency of a ductus arteriosus; mechanical ventilatory and/or mechanical circulatory support

Coding Implications

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CPT® Codes	Description
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

Reviews, Revisions, and Approvals	Revision Date	Approval Date
New policy developed, specialist reviewed	12/16	01/17
Code I25.1 changed to I25.10. In D.15, replaced “Class II or III obesity (body mass index ≥ 35.0 kg/m ²) with BMI $\geq 120\%$ of the 95th percentile and added a link to the CDC clinical growth Charts. Added Appendix A with the 95th percentile values. Specialist reviewed.	01/20	01/20
Edited malignancy contraindication to not specify within 2 years, and added exceptions of cancer that has been completely resected, or that has been treated and poses acceptable future risk. Removed coronary artery disease not amenable to revascularization from list of contraindications.	05/20	05/20
Reformatted criteria to group all class C heart failure scenarios together and added additional exclusion of ruling out reversible causes of heart failure. References reviewed and updated. Replaced “member” with “member/enrollee” in all instances.	12/20	12/20
In I.C., replaced “adequate functional status with ability for rehabilitation” and contraindications regarding past or current nonadherence to medical therapy, and psychological condition associated with the inability to comply with medical therapy with “Inability to adhere to the regimen necessary to preserve the transplant, even with caregiver support.” Changed “review date” in header to “Date of Last Revision” and “Date” in the revision log header to “Revision Date.”	08/21	08/21
Annual review. Revised I.C.13, from “BMI $\geq 120\%$ of the 95th percentile (varies by sex and age)” to “BMI ≥ 35 or BMI $\geq 120\%$ of the 95th percentile (varies by sex and age), whichever is lower.” References reviewed and updated. Reviewed by specialist.	12/21	12/21

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Moved criterion “all reversible causes of heart failure have been ruled out...” to I.C, and moved contraindications to I.D. Edited contraindications: added GFR rate; added “Acute liver failure or cirrhosis...”, added acute renal failure; added HIV infection with detectable viral load; added septic shock; added progressive cognitive impairment; replaced “untreatable significant dysfunction of another major organ system..” with “Other severe uncontrolled medical condition expected to limit survival after transplant”; slightly reworded substance use contraindication; removed “acute medical instability...” and “uncorrectable bleeding diathesis;” replaced “malignancy, except for non-melanoma...” with “Malignancy with high risk of recurrence or death related to cancer.”	02/22	02/22
Changed description and header of BMI charts from mentioning “male” and “female” to “those with a male reproductive system” and “those with a female reproductive system.”	09/22	
Annual review. Appendix A tables updated to remove dashes. Removed ICD-10 codes. References reviewed and reformatted.	12/22	12/22
Annual review. Added additional criteria I.A.1.b.vi.a., pulmonary hypertension and a potential risk of developing fixed, irreversible elevation of pulmonary vascular resistance that could preclude orthotopic heart transplantation in the future. Updated I.D.1. from GFR < 40 mL/min/1.73m ² to GFR < 30 mL/min/1.73m ² . Expanded I.D.2. with qualifying criteria for members who are HIV positive. Updated I.D.21. to exclude marijuana use when prescribed by a licensed practitioner and include required commitment to reducing substance use behaviors if urgent transplant timelines are present. Background reviewed and updated. References reviewed and updated. Reviewed by external specialist.	10/23	10/23
Annual review. Updated description and background with no clinical significance. References reviewed and updated.	08/24	08/24
Annual review. Updated verbiage in I.D.10. regarding liver disease and removed I.D.18. "BMI ≥ 35 or BMI..." Edit made to I.D.21. removing the sentence "Serial blood and urine..." Removed Appendix A regarding BMI charts. Background updated with no clinical significance. References reviewed and updated. Policy reviewed by internal specialist.	08/25	08/25
Annual review. Removed I.D.6. “Amyloid light chain...”. Under I.D.16. added “irreversible” and “unrelated to the disease process of the organ...”. Removed I.D.19. regarding adequate social system. References reviewed and updated. Reviewed by internal and external specialists.	07/26	07/26

References

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Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted

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

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

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

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

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Note: For Medicaid members/enrollees, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take

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precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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

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