

Clinical Policy: Heart (Cardiac) Transplantation

Reference Number: WNC.CP.202

Last Review Date:

[Coding Implications](#)

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Note: When state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Description¹

Heart (cardiac) transplantation is the surgical excision of a heart and the main arteries from a human, brain-dead donor, with subsequent implantation into a member who has had his heart surgically removed in a similar manner. The new heart is surgically attached to the major blood vessels which include the pulmonary arteries, pulmonary veins, aorta, and the vena cava.

Policy/Criteria¹

- I. WellCare of North Carolina® shall cover *pediatric* heart (cardiac) transplantation when the member meets the following criteria:
 - A. Heart failure with persistent symptoms at rest, requiring **ONE OR MORE** of the following:
 1. Continuous infusion of intravenous inotropic agents;
 2. Mechanical ventilator support; **OR**
 3. Mechanical circulatory support.
 - B. Pediatric heart disease with symptoms of heart failure not meeting the above criteria but having:
 1. Severe limitation of exercise and activity (if measurable, member would have a peak maximum oxygen consumption less than 50% predicted for age and sex);
 2. Cardiomyopathies or previously repaired or palliated congenital heart disease and significant growth failure attributable to the heart disease;
 3. Near sudden death or life-threatening arrhythmias untreatable with medications or an implantable defibrillator;
 4. Restrictive cardiomyopathy with reactive pulmonary hypertension;
 5. Reactive pulmonary hypertension and potential risk of developing fixed, irreversible elevation of pulmonary vascular resistance that could preclude orthotopic heart transplantation in the future;
 6. Anatomical and physiological conditions likely to worsen the natural history of congenital heart disease in infants with a functional single ventricle; **OR**
 7. Anatomical and physiological conditions that may lead to consideration for heart transplantation without systemic ventricular dysfunction.

CLINICAL POLICY WNC.CP.202
HEART (CARDIAC) TRANSPLANTATION

- II.** WellCare of North Carolina[®] shall cover heart (cardiac) transplantation for *adult* members with end-stage, irreversible, refractory, symptomatic heart disease requiring maximal continuous medical or mechanical support **AND** who have:
- A.** A low functional status;
 - B.** A poor probability of survival; **AND**
 - C. One** of the following underlying conditions:
 - 1. Presence of an implanted ventricular assist device;
 - 2. Refractory cardiogenic shock;
 - 3. Dependency on intravenous inotropic support to maintain adequate organ perfusion;
 - 4. Maximal peak venous oxygenation (V02) of 11-14 milliliters/kilogram/minute (or 55% of predicted) and major limitation of activities;
 - 5. Severe ischemia (or recurrent unstable ischemia) consistently limiting routine activity not amenable to bypass surgery or percutaneous coronary intervention;
 - 6. Recurrent symptomatic ventricular arrhythmias refractory to all therapeutic modalities; **OR**
 - 7. Ischemic cardiomyopathy not amenable to medical therapy or revascularization procedures.
- III.** Retransplantation in a member with graft failure, due to either technical reasons or hyperacute rejection is considered medically necessary.
- IV.** Retransplantation in a member with chronic rejection, moderate graft vasculopathy or recurrent disease is considered medically necessary when the member meets the general section criteria as outlined above.
- V.** The member and caregiver are willing and capable of complying with the post-transplant treatment plan.
- VI.** WellCare of North Carolina[®] **shall not** cover heart (cardiac) transplantation when:
- A. Any** of the following clinical conditions are present:
 - 1. Alcoholic cardiomyopathy (unless abstinent for at least six months);
 - 2. Systemic illness that would limit life expectancy or compromise recovery from cardiac transplantation;
 - 3. Diabetes mellitus with evidence of significant end-organ complications, such as retinopathy, neuropathy, nephropathy, and peripheral or cerebrovascular disease;
 - 4. Acute severe hemodynamic compromise at the time of transplant, when accompanied by failure of any vital end-organ, because survival is likely to be compromised;
 - 5. Severe peripheral vascular disease or cerebrovascular disease;
 - 6. Current, potentially life-threatening malignancy;
 - 7. Active infection (except for infection of a ventricular assist device);

CLINICAL POLICY WNC.CP.202
HEART (CARDIAC) TRANSPLANTATION



8. Irreversible hepatic (liver) dysfunction (transaminases twice normal, with associated coagulopathy), irreversible renal (kidney) dysfunction (serum creatinine greater than 2 mg/dl or creatinine clearance less than 50 cc/min);
 9. Chronic bronchitis or chronic obstructive pulmonary disease (forced expiratory volume in one second (FEV I) less than 60% predicted) or any irreversible lung disease;
 10. Cachexia, even without major end-organ failure, as survival is significantly less favorable;
 11. Human Immunodeficiency Virus (HIV) positivity;
 12. Morbid obesity indicated by either a body mass index (BMI) greater than 40, or a BMI greater than 35 with comorbid conditions;
 13. Absence of documentation of nonsmoking status;
 14. Recent substance use that will likely impair compliance with post-transplant protocols;
 15. Member's psychosocial history limits the member's ability to comply with pre-and post-transplant medical care, **or**
 16. Current member/caretaker non-compliance would make compliance with a disciplined medical regimen improbable.
- B.** Pulmonary infarction or embolism during the preceding eight weeks is considered a relative contra-indication; **or**
- C.** Heart transplants requiring planned concurrent coronary artery bypass graft surgery, as this is considered experimental.

Background¹

WellCare of North Carolina[®] shall require prior approval for heart (cardiac) transplantation. The provider shall obtain prior approval before rendering heart (cardiac) transplantation. Only those members accepted for transplantation by a transplantation center and eligible for transplant listing shall be considered for prior review. Guidelines must be followed for transplant network or consortiums, if available.

Coding Implications

This clinical policy references Current Procedural Terminology (CPT[®]). CPT[®] is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2024, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

**CLINICAL POLICY WNC.CP.202
HEART (CARDIAC) TRANSPLANTATION**



CPT®* Codes	Description
33945	Heart transplant, with or without recipient cardiectomy

Reviews, Revisions, and Approvals	Date	Approval Date
Original approval date	04/21	05/21
Reviewed CPT codes.	04/22	05/22
Annual Review. CPT code 33940 removed. NCHC verbiage removed from NC Guidance Verbiage.	05/23	05/23
Annual Review. Removed ICD-10-CM code & HCPCS tables.	02/24	02/24
Annual Review. Removed “Medicaid and health choice” verbiage from References.		

References

1. State of North Carolina Medicaid Clinical Coverage Policy No: 11B-2 Heart (Cardiac) Transplantation. [Program Specific Clinical Coverage Policies | NC Medicaid \(ncdhhs.gov\)](https://www.ncdhhs.gov/Program-Specific-Clinical-Coverage-Policies-NC-Medicaid). Published August 15, 2023. Accessed November 5, 2024.

North Carolina Guidance

Eligibility Requirements

- a. An eligible beneficiary shall be enrolled in the NC Medicaid Program (Medicaid is NC Medicaid program, unless context clearly indicates otherwise);
- b. Provider(s) shall verify each Medicaid beneficiary’s eligibility each time a service is rendered.
- c. The Medicaid beneficiary may have service restrictions due to their eligibility category that would make them ineligible for this service.

EPSDT Special Provision: Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age

- a. 42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]
Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiary under 21 years of age if the service is medically necessary health care to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed practitioner).

This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his or her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

CLINICAL POLICY WNC.CP.202 HEART (CARDIAC) TRANSPLANTATION



Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product or procedure:

1. that is unsafe, ineffective, or experimental or investigational.
2. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT and Prior Approval Requirements

1. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does NOT eliminate the requirement for prior approval.
2. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *NCTracks Provider Claims and Billing Assistance Guide*, and on the EPSDT provider page. The Web addresses are specified below:

NCTracks Provider Claims and Billing Assistance Guide:

<https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html>

EPSDT provider page: <https://medicaid.ncdhhs.gov/>

Provider(s) Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for the procedure, product, or service related to this policy, the provider(s) shall:

- a. meet Medicaid qualifications for participation;
- b. have a current and signed Department of Health and Human Services (DHHS) Provider Administrative Participation Agreement; and
- c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

Compliance

Provider(s) shall comply with the following in effect at the time the service is rendered:

- a. All applicable agreements, federal, state and local laws and regulations including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements; and

CLINICAL POLICY WNC.CP.202
HEART (CARDIAC) TRANSPLANTATION



- b. All NC Medicaid's clinical (medical) coverage policies, guidelines, policies, provider manuals, implementation updates, and bulletins published by the Centers for Medicare and Medicaid Services (CMS), DHHS, DHHS division(s) or fiscal contractor(s).

Claims-Related Information

Provider(s) shall comply with the NC Tracks Provider Claims and Billing Assistance Guide, Medicaid bulletins, fee schedules, NC Medicaid's clinical coverage policies and any other relevant documents for specific coverage and reimbursement for Medicaid:

- a. Claim Type - as applicable to the service provided:
 - Professional (CMS-1500/837P transaction)
 - Institutional (UB-04/837I transaction)Unless directed otherwise, Institutional Claims must be billed according to the National Uniform Billing Guidelines. All claims must comply with National Coding Guidelines.
- b. International Classification of Diseases and Related Health Problems, Tenth Revisions, Clinical Modification (ICD-10-CM) and Procedural Coding System (PCS) - Provider(s) shall report the ICD-10-CM and Procedural Coding System (PCS) to the highest level of specificity that supports medical necessity. Provider(s) shall use the current ICD-10 edition and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for code description, as it is no longer documented in the policy.
- c. Code(s) - Provider(s) shall report the most specific billing code that accurately and completely describes the procedure, product or service provided. Provider(s) shall use the Current Procedural Terminology (CPT), Health Care Procedure Coding System (HCPCS), and UB-04 Data Specifications Manual (for a complete listing of valid revenue codes) and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for the code description, as it is no longer documented in the policy. If no such specific CPT or HCPCS code exists, then the provider(s) shall report the procedure, product or service using the appropriate unlisted procedure or service code.

Unlisted Procedure or Service

CPT: The provider(s) shall refer to and comply with the Instructions for Use of the CPT Codebook, Unlisted Procedure or Service, and Special Report as documented in the current CPT in effect at the time of service.

HCPCS: The provider(s) shall refer to and comply with the Instructions For Use of HCPCS National Level II codes, Unlisted Procedure or Service and Special Report as documented in the current HCPCS edition in effect at the time of service.

- d. Modifiers - Providers shall follow applicable modifier guidelines.
- e. Billing Units - Provider(s) shall report the appropriate code(s) used which determines the billing unit(s).
- f. Co-payments -
For Medicaid refer to Medicaid State Plan:
<https://medicaid.ncdhhs.gov/get-involved/nc-health-choice-state-plan>
- g. Reimbursement - Provider(s) shall bill their usual and customary charges. For a schedule of rates, refer to: <https://medicaid.ncdhhs.gov/>.

CLINICAL POLICY WNC.CP.202 HEART (CARDIAC) TRANSPLANTATION



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 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.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members/enrollees and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers,

CLINICAL POLICY WNC.CP.202
HEART (CARDIAC) TRANSPLANTATION

members/enrollees and their representatives agree to be bound by such terms and conditions by providing services to members/enrollees and/or submitting claims for payment for such services.

©2018 Centene Corporation. All rights reserved. All materials are exclusively owned by Centene Corporation and are protected by United States copyright law and international copyright law. No part of this publication may be reproduced, copied, modified, distributed, displayed, stored in a retrieval system, transmitted in any form or by any means, or otherwise published without the prior written permission of Centene Corporation. You may not alter or remove any trademark, copyright or other notice contained herein. Centene® and Centene Corporation® are registered trademarks exclusively owned by Centene Corporation.

DRAFT