

Clinical Policy: Total Artificial Heart

Reference Number: WNC.CP.122

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.

Description

The SynCardia temporary Total Artificial Heart (TAH) (SynCardia Systems Inc.), formerly known as the CardioWest Total Artificial Heart, is a biventricular pulsatile pump that replaces the patient's native ventricles and valves. This policy describes the medical necessity requirements for the total artificial heart.

Policy/Criteria

- I. It is the policy of WellCare of North Carolina® that the Total Artificial Heart (TAH) is **medically necessary** as a bridge to heart transplantation when all of the following criteria are met:
 - A. Member is approved for cardiac transplant and is currently on transplant list;
 - B. New York Heart Association (NYHA) Functional Class IV;
 - C. Presence of non-reversible biventricular failure unresponsive to all other treatments;
 - D. Ineligible for other ventricular support devices;
 - E. Compatible donor heart is currently unavailable;
 - F. Imminent risk of death;
 - G. The device is approved by the United States Food and Drug Administration (FDA) and used according to the FDA-labeled indications, contraindications, warnings and precautions;
 - H. Member is able to receive adequate anti-coagulation while on the total artificial heart.

- II. It is the policy of WellCare of North Carolina® that there is insufficient evidence to support the use of the Total Artificial Heart as destination therapy (permanent replacement of the failing heart).

Background

Heart transplantation has become the standard treatment for eligible patients with irreversible biventricular failure unresponsive to medical and surgical treatment.¹⁵ The SynCardia temporary Total Artificial Heart (TAH) system is indicated as a bridge to transplantation in cardiac transplant eligible candidates at risk of imminent death from biventricular heart failure. The TAH is a biventricular pulsatile pump that replaces the patient's native ventricles and valves and pumps blood to both the pulmonary and systemic circulations. The system consists of the implantable TAH and an external console connected by drivelines.

There is limited evidence on the use of TAH as a bridge to transplantation as compared with the use of left ventricular assist devices. However, the available evidence demonstrates that the TAH improves survival in transplant-eligible patients with biventricular heart failure at imminent risk of death.¹ Use of the TAH as a bridge to cardiac transplantation continues, but the volume of TAH implantations is very low (fewer than 100 cases per year in the United States).¹³ There is insufficient evidence on the use of TAH as destination therapy.

The TAH was originally approved by the Food and Drug Administration (FDA) for in-hospital use. On June 26, 2014, the FDA approved the SynCardia Freedom portable driver for use in patients who have been implanted with the TAH and are clinically stable. The portable driver allows patients to be discharged from the hospital while waiting for a donor heart.

The SynCardia 50cc temporary Total Artificial Heart (TAH) is a smaller version of the SynCardia 70cc TAH. The 50cc temporary Total Artificial Heart System (50cc TAH-t) has received U.S. FDA approval as a bridge to transplantation in cardiac transplant eligible patients at risk of imminent death from biventricular failure. According to the manufacturer, Syncardia, the device is intended for use as a bridge to transplant in patients with smaller stature (i.e., BSA $\leq 1.85\text{m}^2$) and adequate T10 measurement (posterior sternum to anterior spine measurement at T10) or adequate room in the chest as determined by 3D imaging assessment or by other standard clinical assessments. Per SynCardia, those with a T10 measurement ≥ 10 cm should be considered for the 70cc TAH.¹⁴ Studies evaluating the 50cc TAH is very limited. A review of the SynCardia database between December 1985 and October 2019 identified fifty-one children supported, 36 with the 70 cc TAH-t and 15 with the 50 cc TAH-t with a total support time of 6,243 days.¹² There have been an increase in implants between 2015 and 2019 with a total of 13 patients being converted to the Freedom Driver support, and the majority of implants in the last 5 years have been with the 50 cc TAH-t.¹²

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.

CPT®* Codes	Description
33927	Implantation of a total replacement heart system (artificial heart) with recipient cardiectomy
33928	Replacement or repair of thoracic unit of a total replacement heart system (artificial heart)

Reviews, Revisions, and Approvals	Reviewed Date	Approval Date
Original approval date	02/21	06/21
Reviewed CPT and ICD-10-CM codes.	08/21	11/21
Annual review. Replaced investigational/experimental language in II & III with, “insufficient evidence to support the use of ...” Background updated w/no change to criteria. References reviewed, updated and reformatted.	08/22	08/22
NCHC verbiage removed from NC Guidance Verbiage.	04/23	04/23
Annual review. Background updated with no impact on criteria. References reviewed and updated.	08/23	08/23
Annual review. Removed criteria III “insufficient evidence to support hospital discharge of members/enrollees implanted with the Total Artificial Heart who are supported by portable drivers (e.g. the Freedom Portable Driver).” Updated background with no clinical significance. HCPCS table and ICD-10-CM Codes tables removed.. References reviewed and updated.	11/23	11/23
Annual review. References reviewed and updated.		

References

1. Birks EJ, Mancini D. Treatment of advanced heart failure with a durable mechanical circulatory support device. UpToDate. www.uptodate.com. Published November 9, 2022. Accessed April 24, 2024.
2. Copeland JG, Smith RG, Arabia FA, et al. Total artificial heart bridge to transplantation: a 9-year experience with 62 patients. *J Heart Lung Transplant*. 2004;23(7):823 to 831. doi:10.1016/j.healun.2003.07.024
3. Copeland JG, Copeland H, Gustafson M, et al. Experience with more than 100 total artificial heart implants. *J Thorac Cardiovasc Surg*. 2012;143(3):727 to 734. doi:10.1016/j.jtcvs.2011.12.002
4. Shah NR, Jaroszewski DE, Ashfaq A, et al. SynCardia Portable Freedom Driver: A Single-Center Experience With 11 Patients. *Innovations (Phila)*. 2015;10(3):188 to 194. doi:10.1097/IMI.0000000000000161

5. Feldman D, Pamboukian SV, Teuteberg JJ, et al. The 2013 International Society for Heart and Lung Transplantation Guidelines for mechanical circulatory support: executive summary. *J Heart Lung Transplant*. 2013;32(2):157 to 187. doi:10.1016/j.healun.2012.09.013
6. Kirsch ME, Nguyen A, Mastroianni C, et al. SynCardia temporary total artificial heart as bridge to transplantation: current results at la pitié hospital. *Ann Thorac Surg*. 2013;95(5):1640 to 1646. doi:10.1016/j.athoracsur.2013.02.036
7. Cook JA, Shah KB, Quader MA, et al. The total artificial heart [published correction appears in *J Thorac Dis*. 2017 Mar;9(3):E342]. *J Thorac Dis*. 2015;7(12):2172 to 2180. doi:10.3978/j.issn.2072-1439.2015.10.70
8. Nguyen A, Pozzi M, Mastroianni C, et al. Bridge to transplantation using paracorporeal biventricular assist devices or the syncardia temporary total artificial heart: is there a difference?. *J Cardiovasc Surg (Torino)*. 2015;56(3):493 to 502.
9. Torregrossa G, Morshuis M, Varghese R, et al. Results with SynCardia total artificial heart beyond 1 year. *ASAIO J*. 2014;60(6):626 to 634. doi:10.1097/MAT.0000000000000132
10. Yancy CW, Jessup M, Bozkurt B, et al. 2013 ACCF/AHA guideline for the management of heart failure: executive summary: a report of the American College of Cardiology Foundation/American Heart Association Task Force on practice guidelines. *Circulation*. 2013;128(16):1810 to 1852. doi:10.1161/CIR.0b013e31829e8807
11. Yancy CW, Jessup M, Bozkurt B, et al. 2017 ACC/AHA/HFSA 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. *Circulation*. 2017;136(6):e137 to e161. doi:10.1161/CIR.0000000000000509
12. Villa CR, Moore RA, Morales DL, Lorts A. The total artificial heart in pediatrics: outcomes in an evolving field. *Ann Cardiothorac Surg*. 2020;9(2):104 to 109. doi:10.21037/acs.2020.02.15
13. Mancini D, Anyanwu A. Emergency care of adults with mechanical circulatory support devices. UpToDate. www.uptodate.com. Published June 26, 2023. Accessed April 24, 2024.
14. SynCardia. 50cc Total Artificial Heart. <https://syncardia.com/total-artificial-heart-50-cc-and-70-cc/>. Accessed April 24, 2024.
15. McDonagh TA, Metra M, Adamo M, et al. 2021 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure [published correction appears in *Eur Heart J*. 2021 Oct 14;:]. *Eur Heart J*. 2021;42(36):3599 to 3726. doi:10.1093/eurheartj/ehab368
16. Kirklin JK, Pagani FD, Goldstein DJ, et al. American Association for Thoracic Surgery/International Society for Heart and Lung Transplantation guidelines on selected topics in mechanical circulatory support. *J Thorac Cardiovasc Surg*. 2020;159(3):865-896. doi:10.1016/j.jtcvs.2019.12.021
17. Parker MS, Fahrner LJ, Deuell BPF, et al. Total Artificial Heart Implantation: Clinical Indications, Expected Postoperative Imaging Findings, and Recognition of Complications. *American Journal of Roentgenology*. 2014;202(3):W191-W201. doi:https://doi.org/10.2214/ajr.13.11066

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.

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
- 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.

CLINICAL POLICY WNC.CP.122

Total Artificial Heart

- 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/>.

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,

CLINICAL POLICY WNC.CP.122
Total Artificial Heart



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, 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.