Clinical Policy: Total Artificial Heart

Reference Number: CP.MP.127
Date of Last Revision: 10/22

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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 health plans affiliated with Centene Corporation® that the Total Artificial Heart is **medically necessary** as a bridge to heart transplantation when all of the following criteria are met:
- **A.** Member/enrollee 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/enrollee is able to receive adequate anti-coagulation while on the total artificial heart.

II. It is the policy of health plans affiliated with Centene Corporation that there is insufficient evidence to support the use of the Total Artificial Heart as destination therapy (permanent replacement of the failing heart).

III. It is the policy of health plans affiliated with Centene Corporation that there is 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).

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. There is a paucity of data evaluating the SynCardia Freedom portable driver. A retrospective review of 30 patients who underwent TAH implantation, 11 of whom successfully transferred to portable driver, reported that 90% of the 11 were bridged to transplantation. Five (45.5%) of 11 patients were discharged home and five (45.5%) remained in-patient on the portable driver before transplantation. Six patients (55%) transferred to the portable driver required a return to a main driver console. Two patients were temporarily maintained on the main driver then returned to the Freedom Driver for bridge to transplantation.[2] According to UpToDate, as of 2017, there were fewer than 20 patients out-of-hospital in the United States with TAH.[14]

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 $\leq 1.85 m^2$) 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 are 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 2020, 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)

ICD-10-CM Diagnosis Codes that Support Coverage Criteria

ICD-10-CM Code	Description
I50.20 through I50.23	Systolic (congestive) heart failure
I50.30 through I50.33	Diastolic (congestive) heart failure
I50.40 through I50.43	Combined systolic (congestive) and diastolic (congestive) heart failure
I50.82	Biventricular heart failure
I50.84	End stage heart failure
I50.9	Heart failure, unspecified

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Policy adopted from Health Net NMP188.	9/16	12/16
References reviewed and updated.	11/17	12/17
References and codes reviewed and updated. Changed wording in I.G (criteria related to thoracic space) to allow for either body measurement, not both, to be considered.	12/18	12/18
References reviewed and updated. Specialist review.	11/19	11/19
In I.G, removed specifications about chest size related to the device, and added that the requested device is FDA approved and will be used according to FDA indications, which include chest measurements. Background updated. Specialist review. Replaced "member" with "member/enrollee" in all instances.	10/20	11/20
Annual review. Replaced investigational/experimental language in II & III with, "insufficient evidence to support the use of …" Changed "review date" in the header to "date of last revision" and "date" in the revision log header to "revision date." References reviewed, updated and reformatted.	11/21	11/21
Annual review. Background updated with no impact on criteria. Changed "date" in the revision log header to "revision date." References reviewed and updated. Specialist review.	10/22	10/22

References

1. Birks EJ, Mancini D. Treatment of advanced heart failure with a durable mechanical circulatory support device. UpToDate. www.uptodate.com. Published August 11, 2022. Accessed September 07, 2022.
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. Meyer A, Slaughter M. The total artificial heart. *Panminerva Med* 2011;53:141 to 154.
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 January 06, 2022. Accessed August 30, 2022.
14. SynCardia. 50cc Total Artificial Heart. https://syncardia.com/clinicians/our-products/50cc-total-artificial-heart/. Accessed August 31, 2022. .

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

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 member/enrollees. This clinical policy is not intended to recommend treatment for member/enrollees. Member/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.

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

Note: For Medicaid member/enrollees, 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.

Note: For Medicare member/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.