

Clinical Policy: Total Artificial Heart

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Description

The SynCardia temporary Total Artificial Heart (TAH-t) (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 TAH-t is **medically necessary** as a bridge to heart transplantation when all of the following criteria are met:
 - A. Patient 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. Sufficient space in the chest area vacated by the natural ventricles (generally body surface areas greater than 1.7 m² and a distance between the sternum and the 10th anterior vertebral body measured by computed tomography imaging greater than or equal to 10cm) to support the total artificial heart;
 - H. Patient 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 the TAH-t is **experimental/investigational** for use as destination therapy (permanent replacement of the failing heart).
- III. It is the policy of health plans affiliated with Centene Corporation that hospital discharge of patients implanted with the TAH-t who are supported by portable drivers (e.g., the Freedom portable driver) is **experimental/investigational**.

Background

Heart transplantation has become the standard treatment for eligible patients with irreversible biventricular failure unresponsive to medical and surgical treatment. The SynCardia temporary Total Artificial Heart (TAH-t) system is indicated as a bridge to transplantation in cardiac transplant eligible candidates at risk of imminent death from biventricular heart failure. The TAH-t 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-t and an external console connected by drivelines.

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There is limited evidence on the use of TAH-t as a bridge to transplantation as compared with the use of left ventricular assist devices. However, the available evidence demonstrates that the TAH-t improves survival in transplant-eligible patients with biventricular heart failure at imminent risk of death.¹ There is insufficient evidence on the use of TAH-t as destination therapy.

The TAH-t 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-t 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-t 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 5 (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 At this time, there is insufficient evidence on the safety and efficacy of the SynCardia Freedom portable driver.

Coding Implications

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CPT® Codes	Description
0051T	Implantation of a total replacement heart system (artificial heart) with recipient cardiectomy
0052T	Replacement or repair of thoracic unit of a total replacement heart system (artificial heart)
0053T	Replacement or repair of implantable component or components of total replacement heart system (artificial heart) excluding thoracic unit

ICD-10-CM Diagnosis Codes that Support Coverage Criteria

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

Reviews, Revisions, and Approvals	Date	Approval Date
Policy adopted from Health Net NMP188.	9/16	12/16
References reviewed and updated.	11/17	12/17

References

1. 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 Jul;23(7):823-31.
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3. Shah NR, Jaroszewski DE, Ashfaq A, et al. SynCardia Portable Freedom Driver: A Single-Center Experience With 11 Patients. *Innovations (Phila).* 2015 May-Jun;10(3):188-94
4. Feldman D, Pamboukian SV, Teuteberg JJ, et al. The 2013 International Society for Heart and Lung Transplantation guidelines for mechanical circulatory support. *J Heart Lung Transplant.* 2013;32(2):1-146.
5. Hayes Medical Technology Directory. Total Artificial Heart, Temporary or Permanent, Biventricular Mechanical Circulatory Support Device. May 2015. Annual Review May 2017.
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 May;95(5):1640-6.
7. Meyer A, Slaughter M. The total artificial heart. *Panminerva Med* 2011; 53:141.
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 Jun;56(3):493-502
9. Torregrossa G, Morshuis M, Varghese R, et al. Results with SynCardia total artificial heart beyond 1 year. *ASAIO J.* 2014 Nov-Dec;60(6):626-34.
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.

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.

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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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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Note: For Medicaid members, 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 members, 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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