Clinical Policy: Total Artificial Heart

Reference Number: LA.CP.MP.127 Coding Implications
Date of Last Revision: 08/23 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 Louisiana Healthcare Connections 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 Louisiana Healthcare Connections 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 $\leq 1.85 m^2$) 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 $\geq$ 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

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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	Revision Date	Approval Date
Converted corporate to local policy.	11/2020	
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”	2/22	2/22

Reviews, Revisions, and Approvals	Revision Date	Approval Date
and "date" in the revision log header to "revision date." Added "and may not support medical necessity" to Coding Implications. References reviewed, updated and reformatted.		
Annual review. Background updated with no impact on criteria. Added I50.82 & I50.84 to ICD-10. References reviewed and updated.	12/22	4/3/23
Annual review. Removed criteria III. Updated background with no clinical significance. Removed ICD-10 code table. References reviewed and updated.	08/23	10/30/23

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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 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. LHCC 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.

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