Clinical Policy: Total Artificial Heart

Reference Number: PA.CP.MP.127
Plan Effective Date: 01/2018
Date of Last Revision: 06/2024

Coding Implications
Revision Log

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 PA Health and Wellness® (PHW) 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 PHW 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 ≥ 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	Review Date	Approval Date
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.	01/19	02/19
References reviewed and updated. Specialist review.	05/2020	
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.	06/2021	

Reviews, Revisions, and Approvals	Review Date	Approval Date
Background updated. Specialist review. Replaced "member" with "member/enrollee" in all instances.		
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.	07/22/2022	
Annual review. Background updated with no impact on criteria. Changed "date" in the revision log header to "revision date." Removed criteria III. Updated background with no clinical significance. Removed ICD-10 code table. References reviewed and updated. Specialist review.	07/2023	
Annual review. References reviewed and updated. Reviewed by external specialist.	06/2024	

References

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