Clinical Policy: Total Artificial Heart

Reference Number: PA.CP.MP.127
Effective Date: 01/18
Date of Last Review: 07/26/2022

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 Pennsylvania Health and Wellness® (PHW) that the TAH 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.** The device is U.S. FDA approved and used according to the FDA-labeled indications, contraindications, warnings and precautions;
- **H.** Patient 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).

III. It is the policy of PHW 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. 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] 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 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
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-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	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	

References

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