VHA Office of Integrated Veteran Care
Clinical Determination and Indication
Total Artificial Heart

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I. Disclaimer

This document is currently in draft and is intended to be used as a reference for non-VA providers and not intended to replace clinical judgment when determining care pathways. These guidelines do not guarantee benefits or constitute medical advice.

II. Clinical Determinations and Indications

a. Indications for Total Artificial Heart

The total artificial heart (TAH) is indicated when used as a bridge to heart transplantation for individuals with biventricular heart failure and will be considered **medically necessary** when **ALL** the following criteria are met:

- Veteran meets eligibility for a heart transplant and is awaiting heart transplantation
- Veteran is at risk of imminent death due to biventricular heart failure
- Veteran is ineligible for other univentricular or biventricular support devices
    - E.g., temporary left ventricular assist device (LVAD) and/or right ventricular assist device (RVAD); or extracorporeal membrane oxygenation (ECMO)
- No other medical or surgical treatment options available

Note: The TAH should be only considered when all other medical and/or surgical treatment options have failed or are unavailable.

b. Limitations/ Exclusions & Contraindications

Conditions/indications for which TAH is **not medically necessary** include, but are not limited to, the following:

- Use as destination therapy
    - Permanent replacement of ventricular function

For all conditions/indications not listed in section II.a. of this document, TAH is considered **not medically necessary** due to insufficient evidence of efficacy and safety.

c. Description of Treatment

The TAH is a pulsatile biventricular device that replaces the Veteran's ventricles and all four valves, and pumps blood throughout the circulatory system. The SynCardia temporary CardioWest TAH is the only Food and Drug Administration (FDA)-approved device and is indicated for use as a bridge to heart transplantation for patients at risk for imminent death due to biventricular failure. This device comes in two sizes (50cc and 70cc) and is a temporary measure to maintain normal blood pumping function for patients waiting for a heart transplantation.

A cardiothoracic surgeon removes the Veteran's ventricles and valves and attaches the TAH to the remaining atria and major arteries (pulmonary artery and aorta). The implanted TAH is connected to an external console, which provides power and control to the device, through drivelines and supports pumping blood through the Veteran's circulatory system.

III. Background and Supporting Information

The following information is for reference purposes only in accordance with the medical benefits package outlined in 38 C.F.R. § 17.38 (b). Each subsection supports VA's determinations for medical necessity and alignment with generally accepted standards of medical practice.

a. Background Information Heart Failure

Heart failure, also known as congestive heart failure, is a serious condition when the heart does not pump enough blood to meet the body's needs. According to the Centers for Disease Control and Prevention (CDC), heart failure affects about 6.2 million adults in the U.S. Risk factors for heart failure include coronary artery disease, diabetes, high blood pressure, obesity, valvular heart disease, and other conditions related to heart disease. Lifestyle choices, including the use of alcohol and tobacco, poor diet, and low physical activity may increase the risk for heart failure.

Heart failure may be acute or chronic and can affect one or both sides of the heart. Heart failure is commonly caused by damage to the heart by other medical conditions such as high blood pressure, heart inflammation, coronary artery disease or ischemic heart disease, cardiomyopathy, or arrhythmias.

Diagnosis and Management

Diagnosis of heart failure is dependent on medical and family history, physical exam findings, and results from imaging and blood tests.

Currently, there is no cure for heart failure, but treatments such as lifestyle modifications, medications, medical devices, and procedures may improve the patients' quality of life. For severe cases, a heart transplantation may be an option for permanent treatment.

Mechanical Devices

Depending on the degree of heart failure, treatment may range from medication therapy to mechanical circulatory support. Some patients may only need left or right ventricular heart support with a left ventricular assist device (LVAD) or a right ventricular assist device (RVAD). These devices support the heart's effort to pump blood throughout the body and may be used as a bridge to transplantation or as destination therapy.

Heart Transplantation & Total Artificial Heart

The American Heart Association's clinical practice guidelines for the management of heart failure recommend heart transplantation for selected patients with advanced heart failure refractory to medication therapy, device, and surgical optimization.

The total artificial heart (TAH) has been in development since the mid-1930s, with the first human implantable device receiving FDA approval in 1990. SynCardia's TAH, remains the only FDA approved device in the U.S. and is only approved for use as a bridge to heart transplantation for patients with biventricular heart failure. Successful implantation of the TAH has led to improved post-transplantation survival rates.

b. Research, Clinical Trials, and Evidence Summaries

Multiple retrospective analyses have shown that TAH is clinically effective for critically ill patients with advanced heart failure who do not meet criteria for alternative devices, such as the LVAD. Although many adverse events and complications have been reported, the TAH has shown acceptable outcomes when used as a bridge to transplantation among the critically ill patient population who need temporary biventricular support.

Malas et al. (2023) conducted a single-center, retrospective study to review patients who underwent SynCardia temporary total artificial heart (TAH-t) implantations between the years 2012-2022. The patients were evaluated by a primary outcome of survival post heart transplantation and stratified according to Interagency Registry for Mechanically Assisted Circulatory

Support (INTERMACS) profile 1 vs 2 or greater. Over the study period, 101 TAH-t implantations were performed in 100 patients. Post TAH-t implantation, 61 patients were successfully bridged to transplantation and 39 died on TAH-t support. Similar successful bridge rates were found between INTERMACs profile 1 vs profile 2 or greater patients. Additionally, of the 61 successfully bridged patients, a 5-year post-transplant survival rate was 86.6%, with no difference between outpatient and inpatient transplant recipients. Through this review, researchers found that acceptable outcomes can be achieved in the highest acuity patients using the TAH-t as a bridge to heart transplantation.

Itagaki et al. (2024) conducted a retrospective cohort analysis using the United Network of Organ Sharing Standard Transplant Analysis and Research File to characterize the national trends in the use and outcomes of patients listed for heart transplantation after TAH implantation, as well as to investigate the validity of center volume to outcome association. The researchers evaluated all patients with mechanical support devices that were intended as a bridge to transplantation in the U.S. between 2005 and 2018. Four hundred seventy-one patients were identified who underwent implantation of TAH as a bridge to transplantation, conducted over 161 different transplant centers. Of the 471 patients, 212 underwent TAH implantation at a center that had a cumulative volume of 10 cases or more, whereas 259 patients underwent TAH implantation at a center that had less than a 10-case volume. Patient demographics were mostly comparable between the two groups at the time of TAH implantation. The researcher's primary outcome was all-cause mortality on the TAH or post-transplantation and the secondary outcome was heart transplantation. Of the 471 patients who underwent TAH implantation, 325 (69.0%) were successfully bridged to transplant in a median time of 3.8 months after TAH implantation and 146 patients (31.4%) died on TAH support in a median time of 1.9 months. Of the 146 patients who died on TAH support, 108 had a documented cause of death due to multiorgan failure (40.7%), stroke (16.7%), or infection (14.8%). Additionally, the researchers found there was a significant difference in mortality based on center volume, with a cumulative incidence of mortality of 18.9% at 6 months and 20.3% at 1 year in high-volume centers versus 29.7% at 6 months and 34.4% at 1 year in low-volume centers. Finally, the researchers found that TAH implantation provided acceptable rates of bridge to transplant with a 1-year cumulative incidence of transplantation of 60% and post-transplant survival with 1-year survival of 80%. Overall, researchers concluded that TAH use is low in the U.S., but TAH appears to remain a viable option for patients who require biventricular bridge to transplant, especially in higher-volume centers.

Copeland et al. (2004) conducted a nonrandomized, prospective study to assess the safety and efficacy of the CardioWest TAH in patients at high risk

for death from irreversible cardiac failure. Eighty-one patients received the TAH and were compared to a control group of 35 patients. The rate of survival to transplantation was 79% of the 81 patients that received the artificial heart. Of the 35 patients in the control group, the rate of survival to transplantation was 46%. The one-year survival rate of patients who received the artificial heart was 70% compared to 31% of the control group. Post implantation benefits of the TAH included improved hemodynamics (blood pressure and organ perfusion) resulting in an improvement in the patient's quality of life. Authors concluded that the implantation of the TAH improved the rate of survival leading up to heart transplantation and survival after transplantation.

Nguyen et al. (2017) conducted a retrospective analysis to review the use of SynCardia TAH as a bridge to cardiac transplantation in a sicker patient population. The patients that received the TAH had refractory cardiogenic shock with a mean ejection fraction of 14% and biventricular failure, a patient population known to have poor prognosis. The team found that survival to transplantation ranged greatly, between 26% and 79%, as reported by CardioWest TAH investigators. A recent report by Copeland and colleagues that was included in this analysis, found survival to transplantation rate of 68% and a post-transplant survival of 77%. Authors concluded that the TAH remains a viable option and offers an effective option for bridging critically ill patients awaiting heart transplantation.

Demondion et al. (2013) conducted a retrospective analysis to report the experience of using CardioWest TAH as a bridge to heart transplantation at La Pitie Hospital in Paris, France. The study examined 27 patients who received the TAH, with a focus on outpatient management after hospital discharge. Of the 27 patients implanted with a TAH, 15 (55.5%) died during support and 12 (44.4%) left the hospital with a portable driver. Between home discharge and heart transplant, patients spent 87% of their support time outside the hospital. The team reported that overall post-heart transplant survival, with median follow-up of 20-months, was 91%. Complications were related to hemodynamics, infections, bleeding, or technical problems with the console.

Copeland et al. (2012) conducted a retrospective analysis and reviewed the preoperative condition, mortality, and morbidity of 101 patients who received a TAH as a bridge to heart transplantation. The team reported that 68% of patients survived to transplantation and 77% of those survived post-transplantation. Multiple adverse events were reported with TAH related to bleeding, peripheral emboli, infections, and neurologic complications, but were considered acceptable in a group of critically ill patients. Causes of death reported while on TAH were mainly due to multiple organ failure. The

analysis concluded there is a clinical need for TAH in a select group of patients with advanced life-threatening heart failure with a reasonable complication rate.

c. U.S. Food & Drug Administration (FDA) Information

VA generally only approves use of medical devices that have received at least FDA clearance for 510(k) Premarket Notification. The following device has received Premarket Approval from the FDA and is indicated for use as a bridge to transplant in cardiac transplant-eligible candidates at risk of imminent death from biventricular failure.

To search for devices that have received FDA 510(k) clearance or Premarket Approval (PMA), please visit the FDA Devices database.

Information	Description
Product Name	SynCardia Temporary Cardio West Total Artificial Heart (TAH-t)
PMA Applicant	P030011
Address	1992 E. Silverlake Rd. Tucson, AZ 85713
Approval Date	10/15/2004
Approval Letter	PMA Approval

d. Medicare Coverage Determinations

There are no available Medicare coverage determinations. VA and Medicare are governed by separate laws and regulations; thus, VA coverage determinations may be different.

On December 01, 2020, CMS removed the NCD at § 20.9 of the Medicare National Coverage Determination Manual, ending coverage with evidence development for artificial hearts and permitting Medicare coverage determinations for artificial hearts to be made by the Medicare Administrative Contractors (MACs) under § 1862(a)(1)(A) of the Social Security Act.

NCD Number	Name	Effective Date
None	N/A	N/A

LCD Number	Contractor	Revision Effective Date
None	N/A	N/A

- NCD: National Coverage Determination
- LCD: Local Coverage Determination

e. TRICARE Policy Manual

Available TRICARE coverage determinations are listed below as a resource. VA and TRICARE are governed by separate laws and regulations; thus, VA coverage determinations may be different.

TRICARE Policy Manual 6010.60-M, Chapter 4, Section 24.2

f. Health Care Procedural Coding Information

The following CPT/HCPCS codes listed in this section are provided for informational purposes only. Inclusion or exclusion of a code does not constitute or imply VA coverage or provider reimbursement. Please refer to section II.a. in this document to review clinical indications for medical necessity.

CPT Code	Description
33927	Implantation of a total replacement heart system (artificial heart) with recipient cardiectomy
33928	Removal and replacement of total replacement heart system (artificial heart)
33929	Removal of a total replacement heart system (artificial heart) for heart transplantation (list separately in addition to code for primary procedure)

IV. Definitions

Term	Definition
Anticoagulated	To have the blood thinned to prevent clotting, typically with medication
Arrhythmia	An irregular rate and/or rhythm of the heartbeat
Bridge to transplantation	The use of a device to support cardiac function while waiting for a heart transplant
Cardiogenic shock	When the heart cannot pump enough oxygenated blood to the brain and other organs
Cardiomyopathy	An abnormality of heart muscle function that may result in decreased ability of the heart to pump blood
Destination therapy	Therapy that is final, not a transition or bridge treatment

Term	Definition
Drivelines	The connection between the total artificial heart device with the external console
Embolus/emboli	A blood clot that travels from one area to another in the blood stream and results in tissue damage
Refractory	Resistant or unmanageable
Pulsatile	To rhythmically beat, pulsate or throb
Ventricular	Of relating to the ventricles of the heart

V. References

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VI. CDI History/Revision Information

- Explanation of changes to the CDI

Revision Type	Date of Revision	Update(s) Made to CDI
	MM/DD/YYYY	
	MM/DD/YYYY	