Total Artificial Heart

Coverage Policy

The SynCardia temporary Total Artificial Heart (SynCardia Systems, Inc., Tucson, AZ) is considered medically necessary as a bridge to transplantation in an individual who is transplant-eligible and at risk of imminent death from biventricular failure.

The SynCardia Freedom® Driver System is considered medically necessary in an individual who is clinically stable and discharge is planned following medically necessary implantation of the SynCardia temporary Total Artificial Heart.

The SynCardia temporary Total Artificial Heart or SynCardia Freedom Driver System is considered experimental, investigational or unproven for any other indication.

Overview

This Coverage Policy addresses total artificial heart (TAH), a mechanical circulatory device that has been used primarily to maintain patients until a suitable donor heart is available for transplantation. Currently, the SynCardia temporary Total Artificial Heart (TAH-t) (SynCardia Systems, Inc., Tucson, AZ) is the only TAH available in the United States.

General Background

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer’s particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer’s benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer’s benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.
Heart failure can develop from any condition that overloads, damages, or reduces the efficiency of the heart muscle, impairing the ability of the ventricles to fill with or eject blood. Heart muscle may be damaged by myocardial infarction, coronary artery disease, infection, toxic chemical exposure, or years of untreated hypertension or heart valve abnormality. Treatment of heart failure includes pharmacologic interventions, including diuretics, angiotensin-converting enzyme inhibitors, vasodilators, digitalis, and beta-blockers. Pharmacologic therapy is ineffective in approximately 40% of heart failure patients, however. Heart transplantation is the most effective treatment for advanced heart failure, with most transplant centers achieving one-year survival rates of 85% or greater. Most transplant recipients can expect a ten-year survival of approximately 50%. The demand for donor hearts far exceeds the available supply, however. Cardiac transplant waiting lists have the highest mortality (30%) of any solid organ waiting list.

As patients become more hemodynamically compromised, there is an increased risk of death prior to transplantation, as well as a less favorable outcome following transplantation. External or implantable ventricular assist devices (VADs) are therefore used for many patients with end-stage heart failure while awaiting transplantation. Timely use of VADs may be successful in preventing further deterioration and reversing metabolic, cellular and nutritional compromise. The temporary use of these mechanical devices is referred to as “bridging” to transplant. VADs are usually inadequate as a bridge to transplant for patients with severe biventricular disease, and two paracorporeal devices may be needed. VADs may be contraindicated, however, in those with aortic regurgitation, cardiac arrhythmias, left ventricular thrombus, aortic prosthesis, acquired ventricular septal defect, or irreversible biventricular failure. A total artificial heart (TAH) is a mechanical circulatory device that has been used primarily to maintain patients until a suitable donor heart is available for transplantation. A fully implantable heart may also be considered as a permanent cardiac replacement, or “destination therapy”, for patients with end-stage heart disease who are not candidates for heart transplantation (Bartoli, 2011; Copeland, et al., 2004).

Currently, the SynCardia temporary Total Artificial Heart (TAH-t) (SynCardia Systems, Inc., Tucson, AZ) is the only TAH available in the United States. The AbioCor® Implantable Replacement Heart (IRH) is not currently marketed. The AbioCor IRH was last implanted in the United States in 2009 and is not currently available despite having received FDA Humanitarian Device Exemption (HDE) from the FDA in 2006 (Hayes, 2015, 2017).

The current model of the TAH-t has fixed dimensions and is contraindicated for use in patients with a body surface area (BSA) < 1.7 m², which generally precludes its use in smaller patients, including adolescents and women. In 2015 SynCardia Systems Inc. received approval from the FDA to conduct an Investigational Device Exemption (IDE) clinical study on use of its TAH-t (50 cc) (ClinicalTrials.gov Identifier: NCT02459054). This version is designed for implantation in most women, smaller men, and many adolescents with end-stage biventricular HF. Under the IDE study, the 50-cc TAH-t initially will be available for implantation in 10 pediatric patients aged 10 to 18 years, 10 adult patients aged 19 to 75 years, and 10 patients who would not otherwise qualify under the study criteria (Hayes, 2015; SynCardia Systems Inc., 2017).

In September 2014, SynCardia Systems Inc. received FDA approval to conduct an Investigational Device Exemption (IDE) study using the TAH-t (70 cc) as destination therapy in adult patients who are not transplant candidates (ClinicalTrials.gov Identifier: NCT02232659) (Hayes, 2015; SynCardia Systems Inc., 2017).

U.S. Food and Drug Administration (FDA)
SynCardia temporary Total Artificial Heart (SynCardia Systems, Inc., Tucson, AZ): The SynCardia temporary Total Artificial Heart (TAH-t), formerly referred to as the CardioWest™ Total Artificial Heart, received FDA premarket approval (PMA) on October 15, 2004 as a bridge to transplant in cardiac transplant-eligible candidates at risk of imminent death from biventricular failure. The FDA approval states that the temporary TAH is intended to be used inside the hospital. The CardioWest TAH is a biventricular, pneumatic pulsatile blood pump that fully replaces the patient’s ventricles and all four cardiac valves.

In the United States, until recently, the SynCardia TAH required a large pneumatic driver system that required the patient to be hospitalized and tethered to a driver console. The SynCardia Freedom® Driver System received FDA approval as a supplement to the original PMA on June 26, 2014. The device as modified is marketed under the trade name SynCardia temporary Total Artificial Heart with the Freedom Driver System, and is indicated for use as a bridge to transplantation in cardiac transplant candidates who have been implanted with the temporary...
Total Artificial Heart (TAH-t) and are clinically stable. As with conventional hospital-based pneumatic drivers systems, the Freedom driver connects to the implanted TAH by a flexible pneumatic driveline that enters the body through the skin in the left chest below the ribs. It is powered by two onboard batteries which can be recharged using a standard electrical outlet or car charger. The Freedom Driver has been in use in Europe since 2010.

Literature Review

SynCardia temporary Total Artificial Heart (TAH): Nguyen et al. (2017) retrospectively analyzed the demographics, clinical characteristics and survival of 13 adult patients receiving the TAH. The patients received the TAH for refractory cardiogenic shock secondary to idiopathic (56%) or ischemic (17%) cardiomyopathy and to other various causes (33%). Before implantation, mean ejection fraction was 14% ± 4%, 7 (54%) patients had previous cardiac surgery, 4 (31%) were on mechanical ventilation, and 3 (23%) patients were on dialysis. According to the institutional policy, patients were not allowed to be discharged home with a portable console when these became available in Canada in 2011. The mean duration of TAH support was 46 ± 40 days. Three (23%) patients died while on support after a mean of 15 days. Actuarial survival on support was 77% ± 12% at 30 days after implantation. Complications on support included one stroke, acute respiratory distress syndrome requiring prolonged intubation (n=5 and acute renal failure requiring temporary dialysis (n=5). Ten (77%) patients survived to be transplanted after a mean of 52 ± 42 days of support. Actuarial survival rates after transplant were 67% ± 16% at one month and 56% ± 17% at 1 year after transplantation.

Demondion et al. (2013) conducted a retrospective analysis of clinical and biological data of 27 patients implanted with a Cardiowest (Syncardia) TAH between December 2006 and July 2010 at a single center in France. Fifteen patients (55.5%) died during device support; fourteen between implantation and discharge from intensive care, and one before home discharge. The major cause of death before discharge was multi-organ failure. Twelve (44.4%) patients left the hospital with a Freedom™ or Excor™ portable driver within a median of 88 days (range 35-152) post-implantation. The mean rehospitalization rate was 1.2 per patient, due to device infection (n=7), technical problems with the console (n=3) and other causes (n=4). Between implantation and transplant, patients spent 87% of their support time outside the hospital. All patients who were discharged home with the TAH were subsequently transplanted. One died post-transplant.

Kirsch et al. (2013) conducted a retrospective analysis of demographics, clinical characteristics, and survival of 90 patients bridged to transplantation using the SynCardia t-TAH at a single institution in France between 2000 and 2010. All patients were in cardiogenic shock secondary to idiopathic or ischemic cardiomyopathy or other causes. Prior to implantation, seven patients had cardiac arrest, 27 were on ventilators, and 18 were on extracorporeal life support. The mean duration of support was 84 ± 102 days. Thirty-five patients died while on support after a mean of 62 ± 107 days, respectively. Actuarial survival on the device at 30, 60, and 180 days after implantation was 74% ± 5%, 63% ± 6%, and 47% ± 8%, respectively. Nine patients experienced a stroke while on support, 13 had mediastinitis, and 35 required surgical exploration for bleeding, hematoma or infection. Twelve patients were discharged home, with mobile or portable drivers. Older recipient age and preoperative mechanical ventilation were found to be risk factors for death while on support. Fifty-five patients were transplanted after a mean of 97 ± 98 days of support. Actuarial survival rates were 78% ± 6%, 71% ± 6%, and 63% ± 8% at one, five, and eight years after transplantation. The authors stated that post-transplant survival was similar to that of patients undergoing primary heart transplantation in France.

A case series by Copeland et al. (2012) reported results of SynCardia TAH implantation as a bridge to transplant in 101 consecutive patients from 1993 to 2009 at University Medical Center in Tucson AZ. Sixty five of these patients had previously been reported as part of an institutional investigational device exemption study from 1993-2002 (Copeland et al., 2004, discussed below). Ninety-five percent of patients were Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) I. INTERMACS established seven different profiles for patients being implanted with mechanical circulatory support, ranging from INTERMACS 7, indicating advanced NYHA class III patients, through INTERMACS 1, acute decompensation (Irwin and Rippe, 2011). The mean support time was 87 days (median 53 days, range 1-44 days). Adverse events included stroke (7.9%) and re-operation for hemorrhage (24.7%). The survival to transplantation rate was 68.3%. The causes of death of 32 patients on device support included multiple organ failure (13), pulmonary failure (6) and neurologic injury (4). Survival following transplantation at one, five, and ten years was 76.8%, 60.5%, and 41.2%, respectively. At the time of publication, the longest term survivor was alive16.4 years post-implantation.
Roussel et al. (2009) evaluated comorbidity and survival of patients who received circulatory support with a CardioWest TAH (currently referred to as the SynCardia temporary Total Artificial Heart) while awaiting heart transplantation from 1990–2006 (n=42, 40 men, 2 women) at a single center in France. All patients were in cardiogenic shock despite maximum inotropic support at the time of implantation. Idiopathic or dilated cardiomyopathy was diagnosed in 19 patients and ischemic cardiomyopathy in 18 patients. Other diagnoses included postcardiotomy heart failure, fulminant myocarditis, and primary graft failure-rejection. Fourteen patients were receiving intra-aortic balloon pump support, six were receiving mechanical ventilation, and six had undergone cardiopulmonary resuscitation within the previous 24 hours. The duration of support was 1–292 days (mean 101 ± 86 days). Twelve patients died (28.5%) while receiving device support. Causes of death included multi organ failure, sepsis, acute respiratory distress syndrome, and alveolar hemorrhage. Thirty patients underwent transplantation. Actuarial survival rates for transplanted patients at one, five, and ten years were 90% (n=25) 81% (n=14) and 76% (n=10), respectively. Adverse events included stroke in three patients and infections in 35 patients. Significant device malfunctions occurred in four patients, but no malfunctions led to patient death.

Drakos et al. (2006) conducted a retrospective review of 278 patients who had undergone cardiac transplantation between 1993 and 2002. The study assessed the influence of pre-transplant mechanical circulatory support (MCS) on post-transplant outcomes. The authors stated that MCS before heart transplantation was previously associated with worse post-transplant outcomes than when MCS was not required. The study was intended to test the hypothesis that similar outcomes are now seen, regardless of whether MCS is required, due to changes in technology, expertise, patient selection, and timing of transplantation. Of the 278 patients included in the analysis, 72 had required MCS and 206 patients had not. Six of the 72 patients who required MCS received the CardioWest TAH. One month and one year survival did not differ between the groups (MCS 92% and 85%, respectively; no MCS 97% and 92%, respectively. The percentage of patients free from rejection at one year was also similar (MCS: 52%, no MCS: 52%, p=0.60). The incidence of chronic renal insufficiency was lower in the MCS group (15.3% vs. 37.9%, p=.001).

FDA approval of the CardioWest TAH (currently referred to as the SynCardia temporary Total Artificial Heart) was based on a multicenter controlled clinical trial that demonstrated improved survival rates in selected patients who received the TAH as a bridge to transplant (n=81) compared to a historical control group (n=35) who received a transplant without previous mechanical circulatory support (Copeland, et al., 2004). The inclusion criteria included: eligible for transplantation (according to institutional criteria) New York Heart Association class IV; body-surface area 1.7 to 2.5 m² or a distance of ≥10 cm from the anterior vertebral body to inner table of the sternum at 10th thoracic vertebra on computed tomographic scanning; hemodynamic insufficiency according to either of the following definitions: Cardiac index ≤2.0 liters/min/m² and one of the following: systolic arterial pressure ≤90 mm Hg or central venous pressure ≥18 mm Hg. Two of the following: dopamine at a dose of ≥10 μg/kg of body weight/min, dobutamine at a dose of ≥10 μg/kg/min, epinephrine at a dose of ≥2 μg/kg/min, other cardioactive drugs at maximal doses, use of an intraaortic balloon pump, or use of cardiopulmonary bypass. Exclusion criteria included: use of any vascular assist device; pulmonary vascular resistance ≥640 dyn · sec · cm⁻⁵ · dialysis in previous 7 days; serum creatinine ≥5 mg/dl (440 μmol/liter); cirrhosis with total bilirubin ≥5 mg/dl (29 μmol/liter); cytotoxic antibody ≥10 percent. The primary endpoints of the study included the rates of survival to heart transplantation and of survival after transplantation. All patients were candidates for transplant and were at risk of imminent death from irreversible biventricular failure. The mean time from entry in the study to transplant was 79.1 days for the TAH group and 8.5 days for the control group. A greater percentage of patients in the TAH group survived to transplant than in the control group (79% vs. 46%, respectively). Overall, one-year survival was 70% in the TAH group and 31% in the control group. The survival rates at one and five years after transplantation in the TAH group were 86% and 64%, respectively, compared to 69% and 34% in the control group. Treatment success was achieved in 69% of the patients in the TAH group, compared to 37% in the control group.

An earlier study of one French center’s fifteen-year experience with the Jarvik-7/CardioWest TAH (Leprince, et al., 2003) concluded that the device was a safe and efficient bridge for patients with terminal congestive heart failure awaiting cardiac transplantation. Between 1986 and 2001, 127 patients were bridged to transplantation with the TAH. All were in terminal biventricular failure despite maximum inotropic support. Patients were divided into two groups. Those in Group I had cardiac failure caused by idiopathic or ischemic dilated cardiomyopathy, while those in Group II had cardiac failure caused by diseases of miscellaneous origin. For the most recent
period (1998–2001), 74% of patients in Group I received transplants. Survival on the TAH was not as successful for the more difficult patients in Group II, with 50% of patients receiving transplants.

Several published uncontrolled and nonrandomized controlled clinical trials conducted in heart transplantation centers also concluded that the SynCardia TAH was relatively safe and effective as a bridge to transplantation in carefully selected heart transplant candidates (Copeland, et al., 1996, 1998, 1999, 2001; Arabia, et al., 1997).

Professional Societies/Organizations
The 2013 American College of Cardiology (ACC) American Heart Association Guideline for the Management of Heart Failure (Yancy et al.) includes the following recommendations for durable mechanical circulatory support (MCS). Total artificial hearts are not specifically mentioned in the guideline or in the 2017 focused update of the 2013 guideline (Yancy, et al., 2017).

- MCS is beneficial in carefully selected patients with stage D heart failure with reduced ejection fraction (HFrEF) in whom definitive management (e.g., cardiac transplantation) or cardiac recovery is anticipated or planned. (Level of Evidence: B)
- Durable MCS is reasonable to prolong survival for carefully selected patients with stage D HFrEF. (Level of Evidence: B)

The above recommendations are considered to be Class IIa level of evidence B.

- Class IIa: Benefit >> Risk; Additional studies with focused objectives needed. It is reasonable to perform procedure/administer treatment.
- Level of evidence B: Limited populations evaluated, data derived from a single randomized controlled trial or nonrandomized studies.

Heart Failure Society of America (HFSA): The following recommendation is included in the 2010 Comprehensive Heart Failure Practice Guideline:

- Patients awaiting heart transplantation who have become refractory to all means of medical circulatory support should be considered for a mechanical support device as a bridge to transplant. (Strength of Evidence = B).

Strength of evidence B is described as evidence arising from cohort studies or smaller clinical trials with physiologic or surrogate endpoints. The mechanical support devices mentioned in the guideline text include the CardioWest TAH and several LVADs. The recommendation above does not make a distinction as to indications for use of a TAH versus an LVAD. There has been no update to this guideline since 2010.


Use Outside of the U.S.
The Syncardia Total Artificial Heart received the CE mark on May 16, 2005, and a Class IV license with conditions by Health Canada on October 27, 2005, for use as a bridge to transplant in cardiac transplant-eligible candidates at risk of imminent death from biventricular failure.

The Freedom Driver System, a wearable portable driver, received the CE mark on March 4, 2010. This system replaces the large console typically used with the Syncardia heart, allowing stable patients in Europe to be discharged while awaiting a donor heart.

The 2013 International Society for Heart and Lung Transplantation Guidelines for Mechanical Circulatory Support (Feldman et al.) include the following recommendations pertinent to total artificial hearts.

Class IIa, Level of Evidence C
- Patients with complex congenital heart disease, atypical situs or residual intraventricular shunts who are not candidates for LV support should be considered for a total artificial heart (Class IIa, Level of evidence: C)
• Patients with treatment-refractory recurrent sustained ventricular tachycardia or ventricular fibrillation in the presence of untreatable arrhythmogenic pathologic substrate (e.g., giant cell myocarditis, scar, sarcoidosis), should not be considered for LV support alone, but rather biventricular support or a total artificial heart (Class IIa, Level of evidence: C)

A Class IIa recommendation indicates that the weight of evidence/opinion is in favor of usefulness/efficacy. Level of evidence C indicates a consensus of opinion of the experts and/or small studies, retrospective studies, or registries.

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

<table>
<thead>
<tr>
<th>CPT®* Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>33927</td>
<td>Implantation of a total replacement heart system (artificial heart) with recipient cardiectomy (Code effective 01/01/2018)</td>
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<tr>
<td>33928</td>
<td>Removal and replacement of total replacement heart system (artificial heart) (Code effective 01/01/2018)</td>
</tr>
<tr>
<td>33999†</td>
<td>Unlisted procedure, cardiac surgery</td>
</tr>
<tr>
<td>0051T</td>
<td>Implantation of a total replacement heart system (artificial heart) with recipient cardiectomy (Code deleted 12/31/2017)</td>
</tr>
<tr>
<td>0052T</td>
<td>Replacement or repair of thoracic unit of a total replacement heart system (artificial heart) (Code deleted 12/31/2017)</td>
</tr>
<tr>
<td>0053T</td>
<td>Replacement or repair of implantable component or components of total replacement heart system (artificial heart) excluding thoracic unit (Code deleted 12/31/2017)</td>
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†Note: When used to report revision or replacement of components only of a replacement heart system (artificial heart).

Considered Medically Necessary when used to report the SynCardia Freedom® Driver System:

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>E1399</td>
<td>Durable medical equipment, miscellaneous</td>
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References


