Total Artificial Heart and Ventricular Assist Devices

Policy Number: CS122.Q
Effective Date: November 1, 2023

Instructions for Use

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Application

This Medical Policy does not apply to the states listed below; refer to the state-specific policy/guideline, if noted:

State	Policy/Guideline
Indiana	None
Kentucky	Total Artificial Heart and Ventricular Assist Devices (for Kentucky Only)
Louisiana	Total Artificial Heart and Ventricular Assist Devices (for Louisiana Only)
Mississippi	Total Artificial Heart and Ventricular Assist Devices (for Mississippi Only)
Nebraska	Ventricular Assist Devices (for Nebraska Only)
New Jersey	Total Artificial Heart and Ventricular Assist Devices (for New Jersey Only)
North Carolina	Total Artificial Heart and Ventricular Assist Devices (for North Carolina Only)
Ohio	Total Artificial Heart and Ventricular Assist Devices (for Ohio Only)
Pennsylvania	Total Artificial Heart and Ventricular Assist Devices (for Pennsylvania Only)
Tennessee	Total Artificial Heart and Ventricular Assist Devices (for Tennessee Only)

Coverage Rationale

The SynCardia™ temporary total artificial heart is proven and medically necessary as a bridge to heart transplantation in members who meet all of the following criteria:
- At risk of imminent death from biventricular failure
- Have no other medical or surgical treatment options
- Eligible for heart transplantation
- Have sufficient space in the chest cavity to accommodate the device (generally, this includes individuals who have a body surface area ≥ 1.7 m^2 for the 70 cc device and a body surface area of ≤ 1.85 m^2 for the 50 cc device)

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Ventricular Assist Devices (VADs), also known as Mechanical Circulatory Support Devices (MCSD)

Optum has established an infrastructure to support the review, development, and implementation of comprehensive clinical guidelines. The evidence-based clinical guidelines are available at Mechanical Circulatory Support Devices.

Documentation Requirements

Benefit coverage for health services is determined by federal, state, or contractual requirements that may require coverage for a specific service. The documentation requirements outlined below are used to assess whether the member meets the clinical criteria for coverage but do not guarantee coverage of the service requested.

Required Clinical Information
Total Artificial Heart
For any services related to total artificial heart, the provider should call the number on the member's ID card.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

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)
33975	Insertion of ventricular assist device; extracorporeal, single ventricle
33976	Insertion of ventricular assist device; extracorporeal, biventricular
33979	Insertion of ventricular assist device, implantable intracorporeal, single ventricle
33981	Replacement of extracorporeal ventricular assist device, single or biventricular, pump(s), single or each pump
33982	Replacement of ventricular assist device pump(s); implantable intracorporeal, single ventricle, without cardiopulmonary bypass
33983	Replacement of ventricular assist device pump(s); implantable intracorporeal, single ventricle, with cardiopulmonary bypass
33995	Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; right heart, venous access only
33997	Removal of percutaneous right heart ventricular assist device, venous cannula, at separate and distinct session from insertion

CPT® is a registered trademark of the American Medical Association

Description of Services

Total artificial hearts (TAH) are mechanical circulatory support devices (MCSD) used as a bridge to heart transplantation in individuals with irreversible biventricular heart failure (HF) in order to prolong survival and improve quality of life. Total artificial hearts are being investigated as a long-term alternative in individuals with end-stage HF ineligible for heart transplantation, referred to as destination therapy (DT).

The SynCardia system is an implantable, pulsatile biventricular device that serves as a total replacement for both ventricles and all four native valves. The device consists of an internal pump and a pneumatic driver housed in an external console. A

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wearable driver system that allows patients to leave the hospital is also available. The SynCardia TAH has been functioning as a biventricular failure option for over 20 years, and for now represents the only Food and Drug Administration (FDA) approved long-term biventricular replacement option (Maynes et al., 2020; Cook et al., 2015).

Clinical Evidence

Malas et al. (2023) used a prospective institutional database to identify 100 patients who underwent 101 temporary total artificial heart (TAH-t) implantations at a single-center high-volume center. The Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) profile at the time of implantation was used to classify and compare patients into those with INTERMACS profile 1, or profile 2, or greater. Median follow-up after transplantation was 4.6 years and median follow-up on device support was 94 days. Overall, 61 patients (61%) were successfully bridged to transplantation and 39 (39%) died on TAH-t support. Successful bridge rates between INTERMACS profile 1 and INTERMACS profile 2 or greater patients were similar (55.6% vs. 67.4%, respectively; P = .50). The most common adverse events on TAH-t support included infection (rates per 100 patient-months: 15.8), ischemic stroke (4.6), reoperation for mediastinal bleeding (3.5), and gastrointestinal bleeding requiring intervention (4.3). The most common cause of death on TAH-t support was multisystem organ failure (n = 20, 52.6%). Thirty-day survival after transplantation was 96.7%; survival at six months, one year, and five years after transplantation was 95.1%, 86.6%, and 77.5%, respectively. The authors concluded that TAH-t demonstrates an excellent bridging and posttransplant survival even when used with the highest-acuity patients. Limitations include the retrospective nature of the study, single-center design, and lack of comparison with other forms of mechanical circulatory support bridge strategies.

Coyan et al. (2022) conducted a single-arm study using the United Network for Organ Sharing (UNOS) database to assess waitlist characterization and posttransplant outcomes of patients who underwent bridge to transplantation (BTT) therapy with the TAH system since its approval in 2004. Adults that were listed in the UNOS system for heart transplantation between 2004 and 2020, were included in the study. One-year survival following heart transplantation after BTT with TAH was the primary outcome. Waitlist deterioration and risk factors for waitlist or posttransplant mortality were the secondary outcomes. During the study 433 total patients underwent TAH implant as BTT therapy; 236 (54.4%) were listed with the TAH, while the remaining patients were upgraded to TAH support while on the waitlist. Waitlist mortality was 7.4%, with 375 patients (86.6%) ultimately being transplanted. Age, cerebrovascular disease, functional status, and ventilator dependence were risk factors for waitlist mortality. One-year survival following successful BTT was 80%. Risk factors for mortality following BTT included age, body mass index, and underlying diagnosis. The authors concluded patients undergoing BTT with TAH had acceptable waitlist survival and good one-year survival. The authors note that proper patient identification for TAH BTT therapy appeared to be the largest outstanding factor and suggest that evolving risk-score development using preoperative data to predict posttransplant survival may be of value to biventricular failure patients in the future. Limitations include the retrospective nature of study and lack of comparison group undergoing a different approach.

An ECRI Clinical Evidence Assessment (2022) evaluated how well SynCardia TAH-t functions as BTT in adults with end-stage biventricular HF and how it compares to alternative treatments. The evidence was found to be somewhat favorable. Per ECRI, the evidence indicated that SynCardia is effective for BTT for most patients with biventricular HF with few to no other treatment options. However, comparison of SynCardia with biventricular assist devices (BiVADs) for survival to transplantation and survival after transplantation could not be determined due to very-low-quality evidence and small sample sizes. The assessment does note that studies report comparable mortality rates for SynCardia and BiVAD.

Carrier et al. (2021) conducted a retrospective analysis to determine outcomes after heart transplantation in 217 patients who were supported with a TAH-t as a bridge to transplant in six North American high-volume centers. Survival and adverse events after TAH-t and heart transplantation were the primary endpoints. The mean age of patients was 49 ±12 years, and heart failure etiologies were non-ischemic dilated cardiomyopathy (36%), ischemic (25%), restrictive (12%), and cardiac graft failure (9%). A total of 101 (48%) patients had INTERMACS patient profile 1, and 65 (31%) had INTERMACS patient profile 2. At the end of the study period, 138 of 217 (63.5%) patients had undergone heart transplantation, and 75 (34.5%) patients died before heart transplantation. The mean time between TAH-t implantation and heart transplantation averaged 181 ±179 days (range: 0-849) and the mean follow-up after heart transplantation was 35 ±25 months. The overall survival in the entire cohort was 75%, 64%, and 58% at 1, 2, and 5 years, respectively. Post-transplant survival was 88%, 84%, 79%, and 74% at six months, one year, two years, and five years, respectively. Among the 32 patients (23%) who died after heart transplantation, the main causes of death were chronic allograft vasculopathy (25%), multiorgan failure (21.8%), sepsis (15.6%), and stroke (9%). The authors concluded three fourth of patients who had TAH-t implantation were alive one year after surgery and transplant outcomes in patients

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bridged with TAH-t are similar to those undergoing heart transplantation in identical conditions. Limitations include the retrospective nature of the study, lack of comparison group, and conflicts of interest which may limit the study's conclusions.

Maynes et al. (2020) conducted a systematic review and meta-analysis to compare outcomes of patients undergoing SynCardia TAH and biventricular HeartWare ventricular assist device (Bi-HVAD) support for biventricular HF. Twelve studies comprised of 512 patients in the TAH group versus 38 patients in the Bi-HVAD group were reviewed. Ischemic cardiac etiology was present in 32% of TAH vs. 15% of Bi-HVAD patients. There was a comparable incidence of stroke (TAH 11% vs. Bi-HVAD 13%), and acute kidney injury (TAH 28% vs. Bi-HVAD 27%). Overall infection rate was 67% in TAH and 36% in Bi-HVAD. Driveline infections were comparable between the two groups and although a higher incidence of mediastinitis was found in the Bi-HVAD group there was no statistically significant difference between the groups. Postoperative bleeding was present in 42% of TAH vs. 23% of Bi-HVAD. Patients in the TAH group had shorter duration of support (TAH 71 days vs. Bi-HVAD 167 days). At the mean follow-up time of 120 days, patients in both groups had similar overall mortality (TAH 36% vs. Bi-HVAD 26%), including mortality on device support (TAH 26% vs. Bi-HVAD 21%). Discharge home on support was achieved in 6% of TAH patients vs. 73% of Bi-HVAD, and 68% of TAH patients were transplanted vs. 61% in the Bi-HVAD group. Limitations of the study include differences in patient selection for various procedures and in the comparative analysis, the small number of patients in the Bi-HVAD group, and heterogeneity of the study population. The authors concluded that heart transplant continues to be the best long-term treatment for patients with medically refractory end-stage biventricular HF. However, both Bi-HVAD and TAH can be considered acceptable bridge to transplant options. The study found that patients on Bi-HVAD support were more likely to be able to be discharged home but there was a much longer duration of support. The authors recommend more research to assess patient outcomes following treatment with TAH and Bi-HVAD support. (Kirsch et al., 2012, Nguyen et al., 2017, Copeland et al., 2012, and Roussel et al., 2009, which were previously cited in this policy, were included in this systematic review and meta-analysis).

Thangappan et al. (2020) conducted a retrospective cohort study that analyzed the differences in TAH application and outcomes in patients with and without congenital heart disease (CHD). Data provided by the SynCardia Department of Clinical Research for all TAH implantations worldwide from December 1985 through October 2019. The patients were then separated into groups by preimplantation diagnosis of CHD and non-CHD. A total of 1,876 patients were identified with 80 patients having a diagnosis of CHD. Children had a higher proportion in the CHD cohort and there were significantly more females. CHD patients were more likely to be supported with a 50 cc TAH. Measured outcomes were similar between the CHD and non-CHD patients including survival, support characteristics, frequency of discharge, and positive outcomes. The authors concluded that TAH is effective to support patients with CHD when VAD therapy alone is not possible due to residual anatomic or physiologic abnormalities. Limitations are noted to be the retrospective nature of the study, the pre-consolidated nature of the data provided, and data regarding complications was not available which limits analysis of post-operative outcomes. Additionally, this study did not provide a comparison between TAH and other approaches for patients with CHD.

Using INTERMACS data, Arabía et al. (2018) evaluated the patient population (n = 450) who received a temporary TAH as a bridge to transplant or as a bridge to decision. Survival, adverse events and competing outcomes from those who received TAHs between June 2006 through April 2017, were reviewed. Dilated cardiomyopathy and ischemic cardiomyopathy were the two most common diagnoses. There were 266 patients who ultimately underwent transplantation, and 162 died. Overall, 3-,6- and 12-month survival rates were 73%, 62%, and 53%, respectively. The most common cause of death was multisystem organ failure (36%), followed by neurologic injury (18%) and elective withdrawal of support (12%). Risk factors for death were identified as older age, pre-implantation dialysis, higher creatinine and lower albumin levels, and implantation at a low-volume center. The most common early adverse events were bleeding and infection. After three months, minor device malfunction and infection were most prevalent. The likelihood of major infection approached 70% within six months. After TAH implantation, 71% of patients in high-volume centers were alive on the device or had undergone transplantation at 12 months versus 57% in low-volume centers. The authors concluded that experienced centers have better outcomes, likely related to patient selection, patient care, device management and timing of implantation. Organized transfer of knowledge to low-volume centers to improve outcomes was recommended. The findings are limited by lack of comparison group undergoing a different intervention.

Torregrossa et al. (2014) conducted a retrospective study of 10 worldwide centers that implanted a TAH in a total of 47 patients with an implantation duration of one year or more. Clinical data were collected on survival, infections, thromboembolic and hemorrhagic events, device failures, and antithrombotic therapy. The mean age of patients was 50 ±1.57 years, the median support time was 554 days (range 365-1,373 days). The primary diagnosis was dilated cardiomyopathy in 23 patients, ischemic in 15, and "other" in nine. After a minimum of one year of support, 34 patients (72%) were successfully transplanted, 12 patients (24%) died while on device support, and one patient (2%) is still supported (at the time of publication). Five patients (10%) had a

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device failure reported. Major complications were as follows: systemic infections in 25 patients (53%), driveline infections in 13 patients (27%), thromboembolic events in nine patients (19%), and hemorrhagic events in seven patients (14%). The authors concluded that in patients who reached a minimum of one year of support, device failure rate is acceptable and only in two cases was the leading cause of death. Infections and hemorrhagic events were the major causes of death. Their assessment is that of patients who remain supported beyond one year are still likely to survive to transplantation. The findings are limited by lack of comparison group or historical controls.

Demondion et al. (2013) performed a retrospective analysis on patients implanted with a TAH and managed on an outpatient basis using a portable driver. Twenty-seven patients were implanted with the TAH. Fifteen patients (55.5%) died during support. Prior to home discharge, the most frequent cause of death was multi-organ failure (46.6%). Twelve patients were discharged home from hospital within a median of 88 days post-implantation. Mean rehospitalization rate was 1.2 by patient, on account of device infection (n = 7), technical problems with the console (n = 3) and other causes (n = 4). Between discharge and transplant, patients spent 87% of their support time out of hospital. All patients who returned home with the TAH were subsequently transplanted, and one died post-transplant. The authors determined that despite morbidity and mortality occurring in the post implantation period, home discharge with a TAH is possible and portable drivers allow for a safe return home.

Kirsch et al. (2013) performed a retrospective analysis of demographics, clinical characteristics and survival of patients bridged to transplantation using the SynCardia TAH. The device was implanted in 90 consecutive patients (80 males; mean age, 46 ±13 years) suffering cardiogenic shock secondary to idiopathic (n = 40) or ischemic (n = 24) cardiomyopathy or other causes. Before implantation, seven (9%) patients had cardiac arrest, 27 (33%) were on ventilator and 18 (22%) were on extracorporeal life support. Pre-implant creatinine values were 1.7 ±0.97 mg/dL and total bilirubin levels were 45 ±32 μmol/L; mean duration of support was 84 ±102 days. Thirty-five (39%) patients died while on support after a mean of 62 ±107 days. Actuarial survival on device was 74% ±5%, 63% ±6% and 47% ±8% at 30, 60 and 180 days after implantation. While on support, nine (10%) patients suffered stroke, 13 (14%) had mediastinitis and 35 (39%) required surgical re-exploration for bleeding hematoma, or infection. Multivariate analysis revealed that older recipient age and preoperative mechanical ventilation were risk factors for death while on support. Fifty-five (61%) 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 concluded that the SynCardia TAH provided acceptable survival to transplantation rates with a low incidence of neurologic events. Post-transplant survival was similar to that of patients undergoing primary heart transplantation.

In a study submitted to the FDA as part of the premarket approval (PMA) application, Copeland et al. (2004) compared survival of patients (n = 81) after artificial-heart implantation to the survival of control patients (n = 35) who met the same study criteria but for whom the implant was not appropriate. Of the implanted patients, 64 (79%) survived to receive a transplant. Of the control patients, 16 (46%) survived to receive a transplant. 70% of the implanted patients survived one year after study entry compared to 31% of the control patients. 51% of the implanted patients survived five years after study entry compared to 14% of the control patients. A limitation of the study is that the two groups were not completely matched. The control group, compared to the CardioWest-implanted group, had higher rates of ischemic HF, smoking history, anticoagulation therapy, prior cardiac surgery and use of an intra-aortic balloon pump. However, the control patients were also significantly healthier on several baseline indices, such as systolic pressure and pulmonary artery mean pressure.

Clinical Practice Guidelines

American Association for Thoracic Surgery (AATS), International Society for Heart and Lung Transplantation (ISHLT)

In a joint guideline, the AATS and ISHLT note that the majority of patients with hemodynamic decompensation requiring long-term mechanical circulatory support (MCS) can be successfully assisted with a left ventricular assist device (LVAD) alone, despite the nearly uniform presence of some degree of right ventricular (RV) failure. However, there is a group of patients with advanced RV failure who can benefit from initial management with biventricular support that includes biventricular assist devices or TAH. The only TAH that is FDA approved for bridge to transplant was currently undergoing a DT clinical trial. Patients who appear uniquely suited to TAH include those with restrictive and infiltrative cardiomyopathies and certain forms of CHD.

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The guidelines' recommendations are summarized below:

- Patients who undergo placement of temporary MCS (percutaneous VAD or extracorporeal membrane oxygenation) should have RV function evaluated at regular intervals; if it remains poor and patient is a transplant candidate, consideration for biventricular support or TAH is advisable.
- The use of biventricular support should be considered for patients who remain in refractory biventricular failure or experience persistent destabilizing ventricular dysrhythmias and have sufficient cavity size for the inflow cannulas. TAH can also be considered in these populations and in patients with infiltrative-restrictive cardiomyopathies, heart graft failure, thrombosed ventricles, and some cardiac tumors.
- For patients listed for transplantation with VAD or TAH associated infection, transplantation is generally safe after debridement and drainage of infected collections, appropriate duration of antibiotics tailored to specific organism (with guidance from infectious disease experts), and resolution of bacteremia. Removal of the contaminated system usually enables eradication of infection.
- After transplantation and removal of infected LVAD (or TAH), extensive irrigation with antibiotic solution at time of transplant and prolonged drainage is useful to prevent recurring mediastinal infection.

The authors note that given the experiential nature of complex surgical specialties like MCS, few aspects of standard practice are supported by RCTs. The cited recommendations are a hybrid product of true evidence-based guidelines and expert consensus opinion coupled with a review of the literature (Kirklin et al., 2020).

American College of Cardiology (ACC), American Heart Association (AHA), Heart Failure Society of America (HFSA)

The clinical practice guideline for the management of HF (Heidenreich, 2022) does not specifically address TAH but does provide recommendations regarding MCS:

- In select patients with advanced HFrEF (heart failure with reduced ejection fraction) who have New York Heart Association (NYHA) class IV symptoms despite guideline-directed medical therapy, durable MCS can be beneficial to improve symptoms, improve functional class, and reduce mortality.
- In select patients with advanced HFrEF who have NYHA class IV symptoms who are deemed to be dependent on continuous intravenous inotropes or temporary MCS, durable LVAD implantation is effective to improve functional status, quality of life, and survival.
- In patients with advanced HFrEF and hemodynamic compromise and shock, temporary MCS, including percutaneous and extracorporeal VADs, are reasonable as a "bridge to recovery" or "bridge to decision".

European Society of Cardiology (ESC)

The 2021 ESC guideline for the diagnosis and treatment of acute and chronic HF states that use of MCS, including TAH, is appropriate for bridge to transplant treatment to keep a patient with advanced HF alive who is otherwise at high risk of death before transplantation until a donor organ becomes available. Additionally, the ESC endorses the use of MCS (short-term or long-term) to keep a patient alive until cardiac function recovers sufficiently to remove MCS (McDonagh et al., 2021).

International Society for Heart and Lung Transplantation (ISHLT)

ISHLT published a guideline for management of patients with durable mechanical circulatory support (DMCS), including both single and biventricular support (Saeed et al., 2023). The guideline recommendations for TAH are summarized below:

Evaluation of DMCS Candidates with Congenital Heart Disease:

- Patients with complex congenital heart disease, atypical situs, or residual intraventricular shunts who are not candidates for LV support should be considered for a TAH (Level of evidence: C)

Arrhythmia Therapy:

- 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), a biventricular support or a TAH is preferred over isolated LV support (Level of evidence: C)

DMCS in Adults with Congenital Heart Disease

- In complex CHD patients with biventricular failure having adequate intrathoracic space, BIVADs or TAH may be considered as a bridge to transplant or as destination therapy (Level of evidence: C)

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For patients with failing Fontan circulation, TAH may be a viable option. (Level of evidence: C) Decision for Advancement to TAH or Durable BiVAD Therapy:

- For patients with persistent/incessant arrhythmias, the TAH may offer advantage over BiVAD (Level of evidence: C)

Biventricular Failure – Not on any MCS:

- Selected patients with end-stage heart failure due to CHD should be considered for TAH/BiVAD after an initial evaluation to assess surrogates for RV dysfunction (Level of evidence: C)

Acute Biventricular Failure – Acute Myocardial Infarction:

- Worsening hemodynamics, refractory arrhythmias, or end-organ dysfunction after a trial of temporary MCS support with hemodynamic optimization and complete revascularization may require escalation to BiVAD or TAH as a life-saving maneuver (Level of evidence: C)

Patients with massive myocardial infarction with accompanying anatomic defects, e.g., VSD and wall rupture, not amenable to surgical repair may be considered for TAH. (Level of evidence: C). Special anatomic and physiological considerations:

- Cardiac extirpation and TAH placement are indicated in patients with biventricular failure and difficult-to-repair or untreatable intracardiac shunts arising from congenital or acquired heart disease (Level of evidence: C)
- Selected patients with infiltrative, restrictive or hypertrophic cardiomyopathies should be considered for the total artificial heart when timely heart transplantation is not feasible (Level of evidence: C)
- For selected patients with extensive infective endocarditis or cardiac tumors without atrial involvement, which cannot be managed readily using conventional cardiac surgical techniques, TAH implantation is useful and may be considered (Level of evidence: C)
- In patients with tumors requiring full atrial resection, the use of the TAH should be avoided due to implantation difficulties and risk (Level of evidence: C)

Total Artificial Heart – TAH:

- TAH implantation for a given patient should be determined by a balance of individual patient issues, surgical/HF Team familiarity/experience, system specifications and system availability (Level of evidence: C)
- A chest CT scan analysis should be performed to assess anatomic compatibility before any TAH implantation (Level of evidence: C)
- For the TAH implantation, spine-sternum distance at the level of the mitral valve should be at least 125 mm and in patients with a body surface area ≥ 1.88 m^2 or height ≥ 170 cm (Level of evidence: C)
- The 70 cc SynCardia TAH can be implanted in large adult patients with a BSA of ≥ 1.7 m^2 , and the 50 cc SynCardia TAH for patients ≤ 1.7 m^2 (Level of evidence: A)

National Institute for Health and Care Excellence (NICE)

The National Institute for Health and Care Excellence published an interventional procedures guidance on artificial heart implantation as a bridge to transplantation. Their recommendations state that current evidence on the safety and efficacy of TAH implantation as a bridge to transplantation for end-stage refractory biventricular HF is limited in quality and quantity. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research. They encourage further research into this technically challenging procedure, including well matched comparative studies (2017).

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

SynCardia Temporary Total Artificial Heart

The 70 cc SynCardia Temporary Total Artificial Heart (formerly known as CardioWest) (SynCardia Systems, Inc.) received an Investigational Device Exemption (IDE) on October 16, 1992, to study the CardioWest TAH under strict protocols at selected heart transplantation centers in the United States. In October 2004, the FDA granted marketing approval under the PMA application process for the CardioWest TAH as a bridge to transplantation in cardiac transplant-eligible patients at risk of imminent death from irreversible biventricular failure. Furthermore, the FDA granted marketing approval for the 50 cc SynCardia

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Temporary Total Artificial Heart for bridge to transplantation on March 5, 2020, as a supplement to the original PMA application (P030011).

Additional information is available at:

- http://www.accessdata.fda.gov/cdrh_docs/pdf3/p030011a.pdf
- https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm
- https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P030011S070

(Accessed June 22, 2023)

In a supplement to the original PMA application (P030011), the FDA granted marketing approval for the Freedom® driver system on June 26, 2014. The system is indicated for use as a bridge to transplantation in cardiac transplant candidates who have been implanted with the SynCardia device and are clinically stable.

References

Arabía FA, Cantor RS, Koehl DA, et al. Interagency registry for mechanically assisted circulatory support report on the total artificial heart. J Heart Lung Transplant. 2018 Nov;37(11):1304-1312.

Carrier M, Moriguchi J, Shah KB, et al. Outcomes after heart transplantation and total artificial heart implantation: A multicenter study. J Heart Lung Transplant. 2021 Mar;40(3):220-228.

Cook JA, Shah KB, Quader MA, et al. The total artificial heart. J Thorac Dis. 2015 Dec; 7(12): 2172–2180.

Copeland JG, Copeland H, Gustafson M, et al. Experience with more than 100 total artificial heart implants. J Thorac Cardiovasc Surg. 2012 Mar;143(3):727-34.

Copeland JG, Smith RG, Arabia FA, et al. Cardiac replacement with a total artificial heart as a bridge to transplantation. N Engl J Med. 2004 Aug 26;351(9):859-67.

Coyan GN, Huckaby LV, Diaz-Castrillon CE, et al. Trends and outcomes following total artificial heart as bridge to transplant from the UNOS database. J Card Surg. 2022 May;37(5):1215-1221.

Demondion P, Fournel L, Niculescu M, et al. The challenge of home discharge with a total artificial heart: the La Pitie Salpetriere experience. Eur J Cardiothorac Surg. 2013 Nov;44(5):843-8.

ECRI. SynCardia Temporary Total Artificial Heart (SynCardia Systems, LLC) as a bridge to transplantation. Clinical Evidence Assessment. 2022 Nov.

Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. Circulation. 2022 May 3;145(18):e895-e1032.

Kirklin JK, Pagani FD, Goldstein DJ, et al. American Association for Thoracic Surgery/International Society for Heart and Lung Transplantation guidelines on selected topics in mechanical circulatory support. J Heart Lung Transplant. 2020 Mar;39(3):187-219.

Kirsch M, Mazzucotelli JP, Roussel JC, et al. Survival after biventricular mechanical circulatory support: does the type of device matter? J Heart Lung Transplant. 2012 May;31(5):501-8.

Kirsch ME, Nguyen A, Mastroianni C, et al. SynCardia temporary total artificial heart as bridge to transplantation: current results at la pitié hospital. Ann Thorac Surg. 2013 May;95(5):1640-6.

Malas J, Chen Q, Akhmerov A,. Experience with SynCardia total artificial heart as a bridge to transplantation in 100 patients. Ann Thorac Surg. 2023 Mar;115(3):725-732.

Maynes EJ, O'Malley TJ, Luc JGY, et al. Comparison of SynCardia total artificial heart and HeartWare HVAD biventricular support for management of biventricular heart failure: a systematic review and meta-analysis. Ann Cardiothorac Surg. 2020 Mar;9(2):69-80.

McDonagh TA, Metra M, Adamo M, et al.; ESC Scientific Document Group. 2021 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure. Eur Heart J. 2021 Sep 21;42(36):3599-3726.

National Institute for Health and Care Excellence (NICE). Artificial heart implantation as a bridge to transplantation for end-stage refractory biventricular heart failure. Interventional procedures guidance [IPG602]. Published date: December 2017.

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Nguyen A, Pellerin M, Perrault LP, et al. Experience with the SynCardia total artificial heart in a Canadian centre. Can J Surg. 2017 Dec;60(6):375-379.

Roussel JC, Sénage T, Baron O, et al. CardioWest (Jarvik) total artificial heart: a single-center experience with 42 patients. Ann Thorac Surg. 2009 Jan;87(1):124-9; discussion 130.

Saeed D, Feldman D, Banayosy AE, et al. The 2023 International Society for Heart and Lung Transplantation guidelines for mechanical circulatory support: a 10- year update. J Heart Lung Transplant. 2023 Jul;42(7):e1-e222.

Syncardia Systems, LLC. Website. https://syncardia.com/. Accessed June 22, 2023.

Thangappan K, Ashfaq A, Villa C, Morales DLS. The total artificial heart in patients with congenital heart disease. Ann Cardiothorac Surg. 2020 Mar;9(2):89-97.

Torregrossa G, Morshuis M, Varghese R, et al. Results with SynCardia total artificial heart beyond 1 year. ASAIO J. 2014 Nov-Dec;60(6):626-34.

Policy History/Revision Information

Date	Summary of Changes
11/01/2023	**Related Policies** • Removed reference link to the Medicare Advantage Coverage Summary titled *Cardiac Procedures: Pacemakers, Pulmonary Artery Pressure Measurements and Ventricular Assistive Devices)* **Documentation Requirements** (new to policy) • Added language to indicate the provider should call the number on the member's ID card for any services related to total artificial heart **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information • Archived previous policy version CS122.P

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

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