

Total Artificial Heart and Ventricular Assist Devices (for Ohio Only)

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[➔ Instructions for Use](#)

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Related Policy

- [Clinical Trials \(for Ohio Only\)](#)

Application

This Medical Policy only applies to the state of Ohio.

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 $\geq 1.7m^2$ for the 70cc device and a body surface area of $\leq 1.85m^2$ for the 50cc device).

Ventricular Assist Devices (VAD's) 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 \(MCSD\)](#).

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 MCSs 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. TAHs 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 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

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 50cc 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 prove comparison between TAH and other approaches for patients with CHD.

Using Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) data, Arabia 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 3 months, minor device malfunction and infection were most prevalent. The likelihood of major infection approached 70% within 6 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 365-1373 days). The primary diagnosis was dilated cardiomyopathy in 23 patients, ischemic in 15, and "other" in 9. After a minimum of 1 year of support, 34 patients (72%) were successfully transplanted, 12 patients (24%) died while on device support, and 1 patient (2%) is still supported (at the time of publication). Five patients (10%) had a device failure reported. Major complications were as follows: systemic infections in 25 patients (53%), driveline infections in 13 patients (27%), thromboembolic events in 9 patients (19%), and hemorrhagic events in 7 patients (14%). The authors concluded that in patients who reached a minimum of 1 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 1 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 1 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, 7 (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 μ mol/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, 9 (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 1, 5 and 8 years after transplantation. The authors concluded that the SynCardia t-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 France.

In a single center, retrospective study, El-Hamamsy et al. (2009) reviewed the results of 43 cases involving mechanical circulatory support systems (MCSS) of which 9 were CardioWest devices. Survival to transplantation or recovery was 74%. Only one patient was successfully bridged to recovery. Complications were common and included bleeding, respiratory failure, and renal failure requiring temporary dialysis, infection and neurological events. One patient had device failure. In patients successfully bridged to transplantation, early actuarial survival (one month) following transplantation averaged 71+/-8% and was 57+/-9% at one year. MCSS support with a left ventricular assist device or a total artificial heart provides an effective means of bridging terminally ill patients to transplantation or recovery. Early survival after transplantation shows satisfactory results. However, these results come at the expense of frequent device-related complications, and device failure remains a constant threat. The findings are limited by lack of comparison group or historical controls.

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 an 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 is 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.

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 focused update of the joint guideline for the management of HF (Yancy et al., 2017) does not address TAH. MCS is included in the algorithm for treatment of refractory New York Heart Association (NYHA) class III-IV (Stage D) HFrEF. The purpose of the guideline was to update areas in which new evidence emerged since the 2013 publication.

In a joint guideline (Yancy et al., 2013), the ACC and AHA do not specifically address TAHs but do provide recommendations regarding MCS:

- 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.
- Nondurable MCS, including the use of percutaneous and extracorporeal VADs, is reasonable as a “bridge to recovery” or “bridge to decision” for carefully selected* patients with HFrEF with acute, profound hemodynamic compromise.
- Durable MCS is reasonable to prolong survival for carefully selected* patients with stage D HFrEF.

*Although optimal patient selection for MCS remains an active area of investigation, general indications for referral for MCS therapy include patients with left ventricular ejection fraction (LVEF) < 25% and NYHA class III-IV functional status despite guideline-directed management and therapy, including, when indicated, cardiac resynchronization therapy, with either high predicted 1- to 2-y mortality (e.g., as suggested by markedly reduced peak oxygen consumption, clinical prognostic scores) or dependence on continuous parenteral inotropic support. Patient selection requires a multidisciplinary team of experienced advanced HF and transplantation cardiologists, cardiothoracic surgeons, nurses and, ideally, social workers and palliative care clinicians.

European Society of Cardiology (ESC)

The European Society of Cardiology (ESC) guidelines do not specifically address TAHs but do provide recommendations regarding MCS. The guidelines state that MCS is an umbrella term describing a number of different technologies used to provide both short- and longer-term assistance in patients with either acute or chronic HF. Other terms for these technologies to include Bridge to Decision (BTD), Bridge to Candidacy (BTC), Bridge to Transplantation, Bridge to Recovery (BTR), and DT. Initially MCS was used as a short-term BTT treatment but is now being used long-term, as DT, in patients not eligible for transplantation. The ESC make the following recommendations regarding MCS: short-term MCS should be considered (as a ‘bridge to recovery’) in patients remaining severely hypoperfused despite inotropic therapy and with a potentially reversible cause (e.g., viral myocarditis) or a potentially surgically correctable cause (e.g., acute interventricular septal rupture); short-term MCS may be considered (as a ‘bridge to decision’) in patients deteriorating rapidly before a full diagnostic and clinical evaluation can be made (McMurray et al., 2012).

National Institute for Health and Care Excellence (NICE)

The National Institute for Health and Care Excellence (NICE) 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 70cc 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 50cc-SynCardia Temporary Total Artificial Heart for bridge to transplantation on 3/05/2020 as a supplement to the original PMA application (P030011).

Additional information 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 August 10, 2021)

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.

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Policy History/Revision Information

Date	Summary of Changes
02/01/2023	<ul style="list-style-type: none">Created state-specific policy version
11/01/2021	<p>Coverage Rationale</p> <ul style="list-style-type: none">Updated coverage criteria: replaced criterion requiring “members have sufficient space in the chest cavity to accommodate the device (generally, this includes <i>patients</i> who have a body surface area $\geq 1.7\text{m}^2$)” with “members have sufficient space in the chest cavity to accommodate the device (generally, this includes <i>individuals</i> who have a body surface area $\geq 1.7\text{m}^2$ for the 70cc device and a body surface area of $\leq 1.85\text{m}^2$ for the 50cc device)” <p>Supporting Information</p> <ul style="list-style-type: none">Updated <i>Description of Services</i>, <i>Clinical Evidence</i>, <i>FDA</i>, and <i>References</i> sections to reflect the most current informationArchived previous policy version CS122.M

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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