

TOTAL ARTIFICIAL HEART

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[Instructions for Use](#) ⓘ

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Related Medical Management Guidelines

- [Clinical Trials](#)
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Related Benefit Interpretation Policy

- Transplantation Services

Related Clinical Guidelines

- [Transplant Review Guidelines: Solid Organ Transplantation](#)

COVERAGE RATIONALE

See [Benefit Considerations](#) ⓘ

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 patients who have a body surface area $\geq 1.7m^2$

DOCUMENTATION REQUIREMENTS

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws 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 guideline 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 the member specific benefit plan document 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)

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DESCRIPTION OF SERVICES

Total artificial hearts (TAH) are mechanical circulatory support devices 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).

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 AbioCor replacement heart (AbioMed) was a totally implantable artificial heart intended as a permanent cardiac replacement. The device consisted of an internal thoracic unit, an internal rechargeable battery, an internal miniaturized electronics package and an external battery pack. Although approved by the FDA in September 2006, the AbioCor is no longer being manufactured (Hayes, 2018; Cook et al., 2015).

BENEFIT CONSIDERATIONS

Some Evidence of Coverage documents allow coverage of experimental/investigational/unproven treatments for life-threatening illnesses when certain conditions are met.

Also refer to the Benefit Interpretation Policy titled *Transplantation Services*.

CLINICAL EVIDENCE

In a retrospective review, Nguyen et al. (2017) analyzed the demographics, clinical characteristics and survival of 13 patients who received a SynCardia TAH for refractory cardiogenic shock secondary to idiopathic, ischemic, cardiomyopathy or other various causes. 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 $77\% \pm 12\%$ at 30 days after implantation. Complications on support included stroke ($n=1$, 8%), acute respiratory distress syndrome requiring prolonged intubation ($n=5$, 38%) and acute renal failure requiring temporary dialysis ($n=5$, 38%). Ten (77%) patients survived to be transplanted after a mean of 52 ± 42 days of support. Actuarial survival rates after transplant were $67\% \pm 16\%$ at 1 month and $56\% \pm 17\%$ at 1 year after transplantation. The authors concluded that the TAH provides an alternative with low incidence of neurologic events in extremely fragile and complex patients awaiting heart transplantation.

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.

Kirsch et al. (2013) performed a retrospective analysis of demographics, clinical characteristics and survival of patients bridged to transplantation using the SynCardia t-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 $\mu\text{mol/L}$; 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 $74\% \pm 5\%$, $63\% \pm 6\%$ and $47\% \pm 8\%$ 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 reexploration 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 $78\% \pm 6\%$, $71\% \pm 6\%$ and $63\% \pm 8\%$ 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.

Biventricular support can be achieved using paracorporeal biventricular assist devices (BiVADs), the total artificial heart (TAH) and implantable ventricular assist devices (VADs). Kirsch et al. (2012) evaluated the influence of the device on patient survival. Data from 383 patients (321 men [84%]) undergoing primary, planned biventricular support were analyzed. Mean age was 41.6 ± 14.0 years. Patients were classified as group 1, 255 (67%) with

paracorporeal BiVADs; group 2, 90 (24%) with TAH; and group 3, 38 (10%) with implantable BiVADs. Mean patient support duration was 82.8 ± 107.4 days and similar among groups. Bridging to transplantation was successful in 211 patients (55%) and to recovery in 23 (6%). Mortality on device was similar among groups. TAH patients had a significantly lower stroke rate. Actuarial estimates for survival while on support were $75.2\% \pm 2.3\%$, $64.4\% \pm 2.7\%$, $61.1\% \pm 2.8\%$, and $56.8\% \pm 3.1\%$ at 30, 60, 90 and 180 days, respectively, and were similar among groups. However, TAH patients undergoing prolonged support (≥ 90 days) showed a trend toward improved survival. Actuarial post-transplant survival estimates were, respectively, 81.7 ± 2.7 , 75.3 ± 3.0 , 73.0 ± 3.0 and 64.7 ± 3.7 at 1 month and 1, 3 and 5 years and were similar among groups. The authors concluded that survival while on support and after heart transplantation did not differ significantly in patients supported with paracorporeal BiVADs, implantable BiVADs or the TAH. Patients undergoing prolonged support (>90 days) tended to have improved survival when supported with TAH compared with BiVADs, which may be related to a lower incidence of neurologic events.

Copeland et al. (2012) reported their group's experience with 101 patients using the SynCardia TAH as a bridge to transplant. These patients were not candidates for left ventricular assist device therapy. Ninety-one percent of cases were Interagency Registry for Mechanically Assisted Circulatory Support profile 1, and the remaining 9% of cases were failing medical therapy on multiple inotropic medications. The mean support time was 87 days (median, 53 days; range, 1-441 days). Pump outputs during support were 7 to 9 L/min. Adverse events (AEs) included strokes in 7.9% of cases and take-back for hemorrhage in 24.7% of cases. Survival to transplantation was 68.3%. Causes of death of 32 patients on device support included multiple organ failure (13), pulmonary failure (6) and neurologic injury (4). Survival after transplantation at 1, 5 and 10 years was 76.8%, 60.5% and 41.2%, respectively. The longest-term survivor is currently alive 16.4 years postimplantation.

Torregrossa et al. (2014) conducted a retrospective study of 10 worldwide centers that implanted a TAH in a total of 47 patients. 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.

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 $71 \pm 8\%$ and was $57 \pm 9\%$ 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.

Roussel et al. (2009) conducted a single center, retrospective study of 42 patients receiving the CardioWest TAH. Duration of support was 1 to 292 days. Twelve patients died (28.5%) while receiving device support, and 30 patients (71.5%) underwent transplantation. Actuarial survival rates for the transplanted patients were 90% ($n = 25$), 81% ($n = 14$), and 76% ($n = 10$) at 1, 5, and 10 years, respectively. Causes of death during device support included multiorgan failure in 6, sepsis in 2, acute respiratory distress syndrome in 2, alveolar hemorrhage in 1 and other cause in 1. There were no device malfunctions that led to patient death. AEs included stroke in 3 patients and infections in 35 patients during support. The CardioWest TAH is an excellent bridge-to-transplant device for patients with biventricular failure. The authors stated that this study demonstrates excellent safety, reliability, and efficiency. Exceptional outcome after transplantation underlines its capacity to aid in end-organ recovery.

A retrospective study by Wegner et al. (2000) examined blood loss and transfusion requirements in 94 heart transplant patients who had no prior thoracic surgery ($n=45$), did have prior cardiac surgery ($n=26$), or who received MCS devices including the CardioWest TAH, Thoratec VAD, or Novacor VAD ($n=23$). Patients receiving MCS devices were at higher risk for intraoperative and postoperative bleeding at the time of heart transplantation compared with the other groups. Autotransfusion volume, post-CPB red blood cell (RBC) units per patient, post-CPB fresh frozen plasma (FFP) units per patient, post-CPB platelet units per patient, total RBC units per patient, total FFP units per patient, and total platelet unit per patient were significantly higher than in one or both of the other groups. The authors noted that the inherent risk of bleeding in patients on mechanical support, due to chronic activation of the

coagulant and inflammatory pathways and the chronic anticoagulation protocol during implantation, requires a proactive approach to manage this complication.

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.

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).

The European Society of Cardiology (ESC) guidelines do not specifically address total artificial hearts 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 (BTT), Bridge to Recovery (BTR), and Destination Therapy (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).

Active clinical trials are in progress for the SynCardia total artificial heart, including destination therapy for the 70cc device, and as a bridge to transplant for the 50cc device. For more information, go to www.clinicaltrials.gov. (Accessed June 4, 2019)

Professional Societies

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

The focused update of the joint guideline for the management of HF (Yancy et al., 2017) does not address total artificial hearts. MCS is included in the algorithm for treatment of refractory NYHA class III-IV (Stage D) HF. 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 total artificial hearts but do provide recommendations regarding MCS:

- MCS is beneficial in carefully selected* patients with stage D HF rEF in whom definitive management (e.g., cardiac transplantation) or cardiac recovery is anticipated or planned.
- Nondurable MCS, including the use of percutaneous and extracorporeal ventricular assist devices (VADs), is reasonable as a "bridge to recovery" or "bridge to decision" for carefully selected* patients with HF rEF with acute, profound hemodynamic compromise.
- Durable MCS is reasonable to prolong survival for carefully selected* patients with stage D HF rEF.

*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 GDMT, 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.

Class IIa recommendations (it is reasonable to perform procedure/administer treatment; additional studies with focused objectives needed). Level of Evidence B (limited populations evaluated; recommendation in favor of treatment or procedure being useful/effective; some conflicting evidence from single randomized trial or nonrandomized studies).

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

SynCardia Temporary Total Artificial Heart

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

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>

(Accessed June 2, 2019)

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.

On October 26, 2016, the FDA issued a letter to health care professionals regarding updated results from INTERMACS comparing mortality rates in patients who were initially supported with either the C2 Driver System or the CSS Console. There has continued to be a higher mortality rate for the subgroup of patients requiring pre-implant circulatory rescue interventions when using the C2 Driver System compared to those using the CSS Console. The mortality rates for patients who did not require pre-implant circulatory rescue interventions were similar for the C2 Driver System compared to the CSS Console. Additional information available at:

<https://www.fda.gov/medicaldevices/safety/letterstohealthcareproviders/ucm526515.htm> (Accessed June 25, 2019)

Humanitarian Device Exemptions (HDEs) Pending FDA Approval

On April 12, 2012, SynCardia announced that the FDA approved a Humanitarian Use Device (HUD) designation for the 70cc SynCardia Total Artificial Heart to be used for destination therapy in addition to its current PMA approval as a bridge to transplant. The FDA has also approved an Investigational Device Exemption (IDE) clinical study to support FDA approval of a Humanitarian Device Exemption (HDE) application (ClinicalTrials.gov Identifier: NCT02232659).

On Jan. 15, 2013, the FDA granted a HUD designation for the SynCardia 50cc Total Artificial Heart to be used for destination therapy in adults. To be eligible, patients must be at risk of imminent death from non-reversible biventricular HF, not eligible for cardiac transplant and have a body surface area (BSA) between 1.2 and 1.79m².

On Jan. 30, 2013, the FDA granted a HUD designation for the SynCardia 50cc Total Artificial Heart to be used as a bridge to transplant for the treatment of biventricular HF in pediatric patients with a BSA that can sufficiently accommodate the device (i.e., between 1.2 and 1.7m²). SynCardia is conducting an FDA-approved Investigational Device Exemption (IDE) clinical study of the 50cc Total Artificial Heart as a bridge to donor heart transplant (ClinicalTrials.gov Identifier: NCT02459054).

Humanitarian Device Exemption (HDE) is a special regulatory marketing approval that makes the device available on a limited basis provided that: (1) The device is to be used to treat or diagnose a disease or condition that affects fewer than 8,000 individuals in the United States; (2) the device would not be available to a person with such a disease or condition unless the exemption is granted; (3) no comparable device (other than a device that has been granted such an exemption) is available to treat or diagnose the disease or condition; and (4) the device will not expose patients to an unreasonable or significant risk of illness or injury, and the probable benefit to health from using the device outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment.

Humanitarian use devices may only be used in facilities that have established a local institutional review board (IRB) to supervise clinical testing of devices, and after an IRB has approved the use of the device to treat or diagnose the specific rare disease.

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GUIDELINE HISTORY/REVISION INFORMATION

Date	Action/Description
09/01/2019	<p>Template Update</p> <ul style="list-style-type: none"> Added <i>Documentation Requirements</i> section <p>Supporting Information</p> <ul style="list-style-type: none"> Updated <i>Clinical Evidence</i> and <i>References</i> sections to reflect the most current information; no change to <i>Coverage Rationale</i> or <i>Applicable Codes</i> Archived previous policy version MMG128.J

INSTRUCTIONS FOR USE

This Medical Management Guideline provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard benefit plan. In the event of a conflict, the member specific benefit plan document governs. Before using this guideline, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its Policies and Guidelines as

necessary. This Medical Management Guideline is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. UnitedHealthcare West Medical Management Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Member benefit coverage and limitations may vary based on the member's benefit plan Health Plan coverage provided by or through UnitedHealthcare of California, UnitedHealthcare Benefits Plan of California, UnitedHealthcare of Oklahoma, Inc., UnitedHealthcare of Oregon, Inc., UnitedHealthcare Benefits of Texas, Inc., or UnitedHealthcare of Washington, Inc.