Molina Clinical Policy
Heart Transplantation with a Total Artificial Heart (TAH): Policy No. 245

Last Approval: 10/12/2022
Next Review Due By: October 2023

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

A total artificial heart (TAH) is an implantable, pneumatic, biventricular support device that provides a total replacement for both ventricles of the failing heart. There are two objectives of implanting a TAH, the first is as a temporary measure to improve the likelihood of survival before and after heart transplantation in patients with end-stage heart failure (HF) who meet standard, accepted criteria for heart transplantation, who are at imminent risk of death and have no other treatment options, and for whom a compatible donor heart is unavailable. The second objective is for use as destination therapy (permanent use) in patients with severe, irreversible biventricular HF who are not candidates for other therapies, including transplantation. (FDA, 2022; FDA, 2006; FDA, 2004).

The SynCardia temporary Total Artificial Heart TAH-t formerly referred to as the CardioWest™ Total Artificial Heart**,** is the only FDA-approved device for 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. Previously, the SynCardia TAH needed 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 approval on June 26, 2014. The device as modified is marketed under the trade name SynCardia Temporary Total Artificial Heart with the Freedom Driver System; it 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. (FDA, 2022; FDA, 2004).

The AbioCor Implantable Replacement Heart System (no longer manufactured despite FDA approval in 2006) is the first fully implantable prosthetic system, intended for permanent use as destination therapy for individuals with end-stage irreversible, biventricular heart failure that has not responded to optimal medical management. Candidates for this device are ineligible for heart transplant. (FDA, 2006).

COVERAGE POLICY

All transplants require prior authorization from the Corporate Transplant Department. Solid organ transplant requests will be reviewed by the Corporate Senior Medical Director or qualified clinical designee. All other transplants will be reviewed by the Corporate Senior Medical Director or covering Medical Director. If the criteria are met using appropriate NCD and/or LCD guidelines, State regulations, and/or MCP policies the Corporate Senior Medical Director's designee can approve the requested transplant.

Office visits with participating Providers do NOT require prior authorization. Providers should see the Member in office visits as soon as possible and without delay. Failure to see the Member in office visits may be considered a serious quality of care concern.

Pre-Transplant Evaluation

(Birks & Mancini, 2022; Kirklin et al., 2020; Yancy et al., 2020; AMR, 2018; Yancy et al., 2017; Hayes, 2015; Feldman et al., 2013)

Please see *MCP-323 Pre-Transplant Evaluation* for additional criteria and information.

Criteria for transplant evaluation include:

1. History and physical examination; **AND**

2. Psychosocial evaluation and clearance:
   a. No behavioral health disorder by history or psychosocial issues:
      - If history of behavioral health disorder, no severe psychosis or personality disorder;
      - Mood/anxiety disorder must be excluded or treated;
      - Member has understanding of surgical risk and post procedure compliance and follow-up required.

   AND
   b. Adequate family and social support.

AND

3. EKG; **AND**

4. Chest x-ray; **AND**

5. Cardiac clearance in the presence of any of the following:
   a. Chronic smokers; **OR**
   b. Members > 50 years age; **OR**
   c. Those with a clinical or family history of heart disease or diabetes.

AND

6. Pulmonary clearance if evidence of pulmonary artery hypertension (PAH) or chronic pulmonary disease; **AND**

7. Neurological exam and clearance for transplant including **ONE** of the following:
   a. Normal exam by H&P; **OR**
   b. Abnormal neurological exam with positive findings including **ONE** of the following:
      - Lumbar puncture normal cytology; **OR**
      - Lumbar puncture with cytological exam abnormal: CNS disease treated prior to clearance.

AND

8. A Performance Status that includes **ONE** of the following:
   a. Karnofsky score 70-100%; **OR**
   b. Eastern Cooperative Oncology Group (ECOG) Grade 0-2.

AND

9. Lab studies that include:
   a. Complete blood count; kidney profile (blood urea nitrogen, creatinine); electrolytes; calcium; phosphorous; albumin; liver function tests; and coagulation profile (prothrombin time, and partial thromboplastin time);*
   b. Serologic screening for: HIV; Epstein Barr virus (EBV); Hepatitis virus B (HBV); Hepatitis C (HCV); cytomegalovirus (CMV); RPR and/or FTA:*
      - If HIV positive **ALL** of the following must be met:
        i. CD4 count >200 cells/mm-3 for >6 months; **AND**
        ii. HIV-1 RNA undetectable; **AND**
        iii. On stable anti-retroviral therapy >3 months; **AND**
        iv. No other complications from AIDS (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidioides mycosis, resistant fungal infections, Kaposi's sarcoma, or other neoplasm).
      - If abnormal serology, need physician plan to address and/or treatment as indicated.

i. Antinuclear antibody, smooth muscle antibody, antimitochondrial antibody
ii. Ceruloplasmin, α1-antitrypsin phenotype
iii. Alpha-fetoprotein

c. Urine drug screen (UDS) if Member is current or gives a history of past drug abuse.

AND

10. Colonoscopy (if indicated or if Member is age ≥ 50) with complete workup and treatment of abnormal results as indicated; an initial screening colonoscopy after initial negative screening requires a follow-up colonoscopy every 10 years).*

AND

11. Gynecological examination with Pap smear for women ages ≥ 21 to ≤ 65 years of age or if indicated (not indicated in women who have had a total abdominal hysterectomy [TAH] or a total vaginal hysterectomy [TVH]) within the last three years with complete workup and treatment of abnormal results as indicated.

Within the last 12 months:

1. Dental examination or oral exam showing good dentition and oral care or no abnormality on panorex or plan for treatment of problems pre- or post-transplant; **AND**
2. Mammogram (if indicated or > age 40) with complete workup and treatment of abnormal results as indicated;* **AND**
3. PSA if history of prostate cancer or previously elevated PSA with complete workup and treatment of abnormal results as indicated.*

* Participating Centers of Excellence may waive these criteria.

Criteria for Syncardia CardioWest™ Temporary Artificial Heart (TAH)

The Syncardia CardioWest™ temporary Total Artificial Heart (TAH) **may be considered medically necessary** as a bridge to heart transplantation for individuals who have no other reasonable medical or surgical treatment options, who are ineligible for other univentricular or biventricular support devices, and who meet **ALL** of the following criteria:

1. Must be used in accordance with FDA approval; **AND**
2. Eligible and listed for donor organ heart transplantation and meet all of the heart transplant criteria in *MCP-116 Heart Transplantation*; **AND**
3. Member is in imminent danger of dying within 48 hours or is becoming ineligible for transplant; **AND**
4. Meet the criteria of New York Heart Association Functional Class IV**; **AND**
5. Member has a diagnosis of biventricular failure and rapid decompensation; **AND**
6. Unavailability of heart donor and likelihood that Member's condition will deteriorate before a donor can be identified; **AND**

7. None of the following contraindications to artificial heart transplantation are present:
   a. Ineligible for donor heart transplant; **AND**
   b. Insufficient space in the chest area vacated by the native ventricles. Generally, this includes individuals who have body surface areas less than 1.7 m^2, or who have a distance between the sternum and the 10th anterior vertebral body measured by computed tomography imaging (CT scan) less than 10 cm.; **AND**
   c. Inability to be adequately anticoagulated on the CardioWest TAH-t.

**Class IV: Unable to carry on any physical activity without discomfort. Symptoms of heart failure at rest. If any physical activity is undertaken, discomfort increases.

A National Coverage Determination (NCD) for *Artificial Hearts and Related Devices (20.9)* indicates that an artificial heart for bridge-to-transplantation (BTT) **is covered** when performed under coverage with evidence development (CED) when a clinical study meets **ALL** of the criteria outlined in the NCD. An artificial heart for destination therapy (DT) is covered when performed under CED when a clinical study meets **ALL** of the criteria outlined in the NCD.

For Members with Significant or Daily Marijuana Use

1. Documentation of compliance with a physician prescribed and managed program of abstinence, and a reasonable expectation that the Member will be abstinent from marijuana use during the transplant and immediate post-transplant time period. Daily marijuana use is an absolute contraindication for both transplant and pre-transplant evaluation unless there is a state mandate applicable for medical marijuana use and transplants, and there is documentation of Member compliance with a physician prescribed plan of care for prescribed marijuana use.
2. If the Member's marijuana use is in compliance with a formal, State-based program for managed medical marijuana, the request should include:
   - Documentation of the Plan of Care for medical marijuana (including the medical decision making that supports the use of medical marijuana); **AND**
   - Transplant Provider agreement with the Plan of Care (including agreement to be accountable for managing the Member's use of medical marijuana).

Limitations and Exclusions

The SynCardia TAH-t System **is considered experimental, investigational, and unproven** for permanent use as destination therapy.

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

Bridge to Transplant

There is sufficient peer reviewed medical literature that supports the use of the artificial heart as a bridge to cardiac transplantation in patients with biventricular heart failure who meet strict selection criteria and who have no other reasonable treatment options. The publications include multicenter nonrandomized, prospective controlled studies (n=81), large comparative studies (n=43-149), a registry database comparative study (n=2785), multiple case series and retrospective controlled studies. Published data reports that a 79% survival rate has been achieved in patients supported with a Syncardia/CardioWest TAH as bridge-to-transplantation and survival after transplantation at 1, 5, and 10 years was 76.8%, 60.5%, and 41.2%, respectively. Additional studies reviewed include: Cheng et al., 2016; Shah et al., 2016; Nguyen et al., 2015; Ryan et al., 2015; Dowling et al., 2004; Fraizer et al., 2004; Samuels et al., 2003). A summary of relevant studies is outlined below.

Copeland et al. (2021) performed a review of the SynCardia Total Artificial Heart. Of the approximate 2000 implants performed, experienced centers reported that 60-80% of implanted patients have been transplanted and over 80% of those transplanted have lived for over one year. The authors note that the SynCardia TAH has supported potential cardiac recipients with irreversible biventricular failure for up to 6 years, providing physiologic pulsatile flows of 6 to 8 L/min at filling pressures of less than 10 mmHg allowing for optimal perfusion and recovery of organs such as the kidneys and liver. The device provides a method for recovering potential transplant candidates who rapidly decompensate from biventricular failure or who have chronic cardiac failure from a variety of etiologies.

Copeland et al. (2021) conducted a large nonrandomized, prospective study in five centers to assess the safety and efficacy of the CardioWest Total Artificial Heart in transplant-eligible patients at risk for imminent death from irreversible biventricular cardiac failure. The primary end points included the rates of survival to heart transplantation and of survival after transplantation. Eighty-one patients received the artificial-heart device. The rate of survival to transplantation was 79 percent (95 percent confidence interval, 68 to 87 percent). Of the 35 control patients who met the same entry criteria but did not receive the artificial heart, 46 percent survived to transplantation. Overall, the one-year survival rate among the patients who received the artificial heart was 70 percent, as compared with 31 percent among the controls. One-

year and five-year survival rates after transplantation among patients who had received a total artificial heart as a bridge to transplantation were 86 and 64 percent. In conclusion, implantation of the total artificial heart improved the rate of survival to cardiac transplantation and survival after transplantation. This device prevents death in critically ill patients who have irreversible biventricular failure and are candidates for cardiac transplantation.

Maltais et al. (2013) conducted a large registry database comparative study in adults who were treated with a left ventricular assist device (LVAD) or total artificial heart (TAH) before heart transplant. Kaplan-Meier and multivariate Cox regression models were used to identify patient, donor, and device characteristics associated with graft survival. 2,674 patients were treated with a LVAD (HeartMate XVE, 724; HeartMate II, 1,882; HeartWare, 68), and 111 were treated with a TAH. Follow-up averaged 25 + 24 months. Gender mismatch occurred in 23%. Graft survival did not differ between LVAD groups, but TAH was associated with reduced graft survival compared with LVADs. After controlling for device type (LVAD vs TAH), lower recipient pulmonary vascular resistance, shorter ischemic time, younger donor age, donor-to-recipient gender match, and higher donor-to-recipient body mass index ratio were independent predictors of longer graft survival. In conclusion, TAH was associated with reduced graft survival after transplant, and survival did not differ between the LVAD device groups. Additional variables that were independently associated with graft survival were donor age, recipient peripheral vascular resistance, ischemic time, gender match, and donor-to-recipient body mass index ratio. Recognition of these factors may inform decisions regarding device support and donor suitability.

SUPPLEMENTAL INFORMATION

None.

CODING & BILLING INFORMATION

CPT Codes

CPT	Description
33927	Implantation of a total replacement heart system (artificial heart) with recipient cardiectomy
33928	Removal and replacement of total replacement heart system (artificial heart)
33929	Removal of a total replacement heart system (artificial heart) for heart transplantation (list separately in addition to code for primary procedure)
33945	Heart transplant, with or without recipient cardiectomy

HCPCS Codes – N/A

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

10/12/2022	Policy reviewed, no changes to criteria, included section on marijuana use; updated Coding section.
10/13/2021	Policy reviewed, no changes to criteria, updated references.
9/18/2019, 9/16/2020	Policy reviewed, no changes to criteria, updated references.
3/8/2018	Updated exclusions to include the SynCardia TAH-t System for permanent use as destination therapy; professional guidelines and references also updated.
12/16/2015, 9/15/2016, 6/22/2017	Policy reviewed, no changes.
4/6/2015	New policy.

REFERENCES

Government Agencies

1. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database (search: "artificial hearts and related devices"). Available from CMS. Accessed August 15, 2022.
2. Food and Drug Administration (FDA). Pre-market approval (PMA): Syncardia artificial heart (multiple approvals). Available from FDA. Updated August 15, 2022. Accessed August 15, 2022.
3. Food and Drug Administration (FDA). Approval letter: AbioCor Implantable Replacement Heart (HUD #2003-0110). Available from FDA. Published September 5, 2006. Accessed August 15, 2022.
4. Food and Drug Administration (FDA). Pre-market approval (PMA): Syncardia temporary cardiowest total artificial heart (TAH-t) (no. P030011). Available from FDA. Published October 15, 2004. Accessed August 15, 2022.

Evidence Based Reviews and Publications

1. AMR Peer Review. Policy reviewed on January 18, 2018 by an Advanced Medical Reviews (AMR) practicing, board-certified physician in the areas of Internal Medicine, Cardiovascular Disease, and Critical Care.
2. Birks EJ, Mancini D. Treatment of advanced heart failure with a durable mechanical circulatory support device. Available from UpToDate. Updated August 11, 2022. Accessed August 15, 2022. Registration and login required.
3. Hayes. Health technology assessment: Total artificial heart, temporary or permanent, biventricular mechanical circulatory support device. Available from Hayes. Published May 28, 2015. Updated June 17, 2019. Archived June 28, 2020. Accessed August 15, 2022. Registration and login required.

National and Specialty Organizations

1. Feldman D, Pamboukian SV, Teuteberg JJ, Birks E, Lietz K, Moore SA, et al. The 2013 International Society for Heart and Lung Transplantation guidelines for mechanical circulatory support: Executive summary. J Heart Lung Transplant. 2013 Feb;32(2):157-87. doi: 10.1016/j.healun.2012.09.013. Accessed August 15, 2022.
2. Kirklin JK, Pagani FD, Goldstein DJ, John R, Rogers JG, Atluri P, et al. American Association for Thoracic Surgery/International Society for Heart and Lung Transplantation guidelines on selected topics in mechanical circulatory support. J Thorac Cardiovasc Surg. 2020 Mar;159(3):865-896. doi: 10.1016/j.jtcvs.2019.12.021. Accessed August 15, 2022.
3. Yancy CW, Drazner MH, Coffin ST, Cornwell W, Desai S, Erwin JP, et al. 2020 ACC/HFSA/ISHLT lifelong learning statement for advanced heart failure and transplant cardiology specialists: A report of the ACC Competency Management Committee. J Am Coll Cardiol. 2020 Mar, 75 (10) 1212–1230. doi: https://doi.org/10.1016/j.jacc.2019.09.030. Accessed August 15, 2022.
4. Yancy CW, Jessup M, Bozkurt B, et al. 2017 ACC/AHA/HFSA focused update guideline for the management of heart failure: Focused update of the 2013 ACCF/AHA guideline for the management of heart failure – a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Failure Society of America. J Am Coll Cardiol. 2017 Aug, 70 (6) 776–803. https://www.jacc.org/doi/pdf/10.1016/j.jacc.2017.04.025. Accessed August 15, 2022.

Peer Reviewed Publications

1. Cheng A, Trivedi JR, Van Berkel VH, et al. Comparison of total artificial heart and biventricular assist device support as bridge-to-transplantation. J Card Surg. 2016 Oct;31(10):648-653. doi: 10.1111/jocs.12823. Accessed August 15, 2022.
2. Copeland J, Langford S, Giampietro J, Arancio J, Arabia F. Total artificial heart update. Surg Technol Int. 2021 Jun 28;39:39/1449. doi: 10.52198/21.STI.38.CV1449. Accessed August 24, 2022.
3. Dowling RD, Gray LA Jr, Etoch SW, Laks H, Marelli D, Samuels L, et al. Initial experience with the AbioCor implantable replacement heart system. J Thorac Cardiovasc Surg. 2004 Jan;127(1):131-41. doi: 10.1016/j.jtcvs.2003.07.023. Accessed August 15, 2022.
4. Frazier OH, Dowling R, Grey LA, et al. The total artificial heart: Where we stand. Cardiology. 2004;101(1-3):117-21. doi: 10.1159/000075992. Accessed August 15, 2022.
5. Maltais S, Jaik NP, Feurer ID, Wigger MA, Disalvo TG, Schlendorf KH, et al. Mechanical circulatory support and heart transplantation: Donor and recipient factors influencing graft survival. Adult Cardiac. 2013. 96(4);P1252-1258. doi: https://doi.org/10.1016/j.athoracsur.2013.05.043. Accessed August 15, 2022.
6. Nguyen A, Pozzi M, Mastroianni C, et al. Bridge to transplantation using paracorporeal biventricular assist devices or the syncardia temporary total artificial heart: is there a difference? J Cardiovasc Surg (Torino). 2015 Jun;56(3):493-502. Available here. Accessed August 15, 2022.
7. Ryan TD, Jefferies JL, Zafar F, Lorts A, Morales DL. The evolving role of the total artificial heart in the management of end-stage congenital heart disease and adolescents. ASAIO J. Jan-Feb 2015;61(1):8-14. doi: 10.1097/MAT.0000000000000156. Accessed August 15, 2022.
8. Samuels E, Dowling R. Total artificial heart: Destination therapy. Cardiol Clin. 2003 Feb;21(1):115-8. doi: 10.1016/s0733-8651(02)00141-8. Accessed August 15, 2022.
9. Shah KB, Thanavaro KL, Tang DG, Quader MA, Mankad AK, et al. Impact of INTERMACS profile on clinical outcomes for patients supported with the total artificial heart. J Card Fail. 2016 Nov;22(11):913-920. doi: 10.1016/j.cardfail.2016.04.016. Accessed August 15, 2022.

APPENDIX

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*