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

Last Approval: 10/08/2025
Next Review Due By: October 2026

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 **temporary total artificial heart** (TAH-t) is an implantable, pneumatic, biventricular support device that provides a total replacement for both ventricles of the failing heart. The implantation of a total artificial heart is used as a bridge to transplantation measure in patients with end-stage heart failure who meet standard, accepted criteria for heart transplantation, are at imminent risk of death with no other treatment options, and for whom a compatible donor heart is unavailable. The TAH is powered by an external battery powered driver system that delivers air in pulses to the heart's ventricles, closely replicating the natural pumping action of a human heart. The volume of TAH implantations is very low, with fewer than 100 cases per year in the United States (Mancini et al. 2024).

Regulatory Status

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, intended and approved for use inside the hospital. The initial Syncardia TAH was approved on October 14, 2004. This 70cc TAH was indicated for patients with a T10* measurement ≥ 10cm. These patients typically have a body surface area (BSA) ≥ 1.7m^2. The SynCardia Freedom® Driver System received FDA approval as a supplement to the original approval on June 26, 2014. The device 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. On March 5, 2020, Syncardia received approval for the 50cc TAH. This device is for patients with adequate T10 measurement or adequate room in the chest as determined by imaging or other clinical assessments. These patients typically have a BSA ≤1.85^2. SynCardia's temporary TAH-t system is regulated by the FDA under the product code LOZ in the Premarket Approval database.

*Posterior sternum to anterior spine measurement at T10

RELATED POLICIES

MCP-116 Heart Transplant
MCP-459 Pre-Transplant and Transplant Evaluation

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.

Please see *MCP-459 Pre-Transplant and Transplant Evaluation* for pre-transplant criteria and transplant evaluation criteria that must be met prior to solid organ transplant.

Criteria for SynCardia Temporary Artificial Heart (TAH-t) System

The SynCardia temporary Total Artificial Heart (TAH-t) System may be **considered medically necessary** as a bridge to heart transplantation when ALL the following criteria are met:

1. Member meets ALL heart transplant criteria stipulated in *MCP-116 Heart Transplantation*
2. Member is ineligible for other univentricular or biventricular support devices
3. Member has no other reasonable medical or surgical treatment options
4. Temporary artificial heart used in accordance with FDA label
5. Member is in imminent danger of dying within 48 hours or at risk of becoming ineligible for transplant
6. Meet the criteria of New York Heart Association Functional Class IV
7. Member has a diagnosis of biventricular failure and rapid decompensation
8. There is an unavailability of heart donor and likelihood that Member's condition will deteriorate before a donor can be identified
9. In addition to the absolute contraindications in MCP-459 Pre-Transplant and Transplant Evaluation, absence of ALL the following absolute contraindications for artificial heart transplantation:
   a. Ineligible for immediate donor heart transplant
   b. Inability to be adequately anticoagulated on the SynCardia temporary Total Artificial Heart (TAH-t) System and/or thrombophilia

Limitations and Exclusions

The SynCardia temporary Total Artificial Heart (TAH-t) System is considered **experimental, investigational, and unproven** for permanent use as destination therapy and should only be used in an approved heart transplant facility.

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

Non-Randomized Studies, Retrospective Reviews, and Other Evidence

Razumov et al. (2024) performed a retrospective analysis of 196 patients who received total artificial heart (TAH) replacements. The main goals of the study were to assess survival rates and identify factors predicting mortality during TAH support. Secondary outcomes focused on adverse events and survival rates post-heart transplantation. The survival rates at 1, 6, and 12 months were reported as 72%, 41%, and 34%, respectively. The cumulative incidence of heart transplantation while on TAH support was 1% at 1 month, 11% at 6 months, and 23% at 1 year. Adverse events documented included postoperative rethoracotomy (44.4%), neurological complications (64.8%), and gastrointestinal bleeding (24.6%). A total of 35.2% of patients successfully underwent heart transplantation with a median posttransplant survival time of 5.8 years. Post-transplant survival rates at 1, 5, and 10 years were 65%, 58%, and 51%, respectively.

Despite the high mortality associated with biventricular failure, the SynCardia TAH remains a viable temporary option for critically ill patients, especially those who can be bridged to heart transplantation.

Itagaki et al. (2022) queried the United Network of Organ Sharing Standard Transplant Research File between 2005 and 2018 for data from total artificial heart transplants and ran the data through multivariable Cox regression models for risk prediction. The data revealed a total of 471 patients underwent total artificial heart implantation. The 6-month cumulative incidence of mortality on the total artificial heart was 24.6%, paired with a 49% 6-month cumulative incidence of heart transplant. Of 161 transplant centers, 11 centers had cumulative volume of 10 or more implants. Cumulative center volume less than 10 implants were predictive of both mortality on the total artificial heart (hazard ratio, 2.2, 95% confidence interval, 1.5-3.1, P < .001) and post-transplant mortality after a total artificial heart bridge (hazard ratio, 1.5, 95% confidence interval, 1.0-2.2, P = .039). In summation the data indicated that total artificial heart is a viable bridge to heart transplantation, especially in higher volume centers. The revelation of inferior outcomes in lower volume centers indicates targeted training, center certifications, and minimum volume requirements could improve outcomes for patients requiring the total artificial heart.

Chen et al. (2022) queried the United Network of Organ Sharing Standard Transplant Research File between 2005 and 2020 to compare the 392 adults who underwent heart transplantation after receiving the total artificial heart as a bridge treatment (TAH-t BTT) against 11,014 durable left ventricular assist device bridge to transplantation (LVAD BTT) patients and 22,348 de novo heart transplants during the same period in the United States. The data revealed that patients who received TAH-t BTT patients had increased dialysis dependence compared to LVAD BTT and de novo transplants (24.7% vs. 2.7% vs. 3.8%) and higher levels of baseline creatinine and total bilirubin (all p < .001). After heart transplantation, TAH-t BTT patients were more likely to die from multiorgan failure in the first year (25.0% vs. 16.1% vs. 16.1%, p = .04); however, of those who survived the first-year post-transplant the 10-year survival rate was similar across the board (TAH-t BTT 66.8%, LVAD BTT 68.7%, De Novo 69.0%, all p > .20). Among TAH-t BTT patients, predictors of 1-year mortality included higher baseline creatinine and total bilirubin, mechanical ventilation, and cumulative center volume <20 cases of heart transplantation involving TAH-t BTT (all p < .05). TAH-t BTT survival rates are acceptable, better at higher volume centers, and the patients who survive the first-year post heart transplantation face similar mortality risks over time when compared to LVAD BTT and de novo heart transplant recipients.

Carrier et al. (2021) conducted a retrospective analysis of 217 consecutive patients who received total artificial heart transplants as a bridge to heart transplantation from 2014 – 2019 in six high volume North American centers. Of the 217 total artificial heart transplants 138 underwent heart transplant, while 75 (34.5%) died before they could receive a heart transplant. The mean time between total artificial heart transplant and heart transplant averaged 181 ± 179 days (range: 0-849) and the mean follow-up after heart transplant 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 6 months, 1 year, 2 years, and 5 years, respectively. In summation, almost two thirds of those who received a total artificial heart could be transplanted with overall and post heart transplantation satisfactory survival rates.

Villa et al. (2020) evaluated the use of the SynCardia TAH in pediatric patients with end stage biventricular heart failure. The study included 51 children and adolescents who received the device as a bridge to cardiac transplantation. 36 patients received the 70cc device and 15 received the 50cc device. The average support duration was 145 days and 113 days for 50 cc and 70cc TAH patients, respectively. The majority of patients were supported for 6 months or less. Overall survival was reported at 71%, with a total of 35 patients being successfully supported transplantation. The study highlights that the introduction of the 50cc TAH model has significantly expanded access to mechanical circulatory support for smaller patients, particularly those with the body surface area BSA less than 1.7 M^2. It also emphasizes the importance of anatomical fit assessments, including T10 measurement and 3D imaging in determining device suitability. The authors conclude that the TAH is a viable and increasingly effective bridge to transplantation in pediatric populations, with advances in device sizing and imaging techniques contributing to improved access and outcomes.

Morshuis et al. (2020) conducted a retrospective analysis of 193 patients who received a total artificial heart as a bridge to transplantation (TAH-t BTT) at a high-volume German center from 2001 – 2019. The 69 TAH-t BTT patients who received heart transplants were compared to 393 left ventricular assist device bridge to transplantation (LVAD BTT), 70 biventricular assist device bridge to transplantation (BVAD BTT), and 876 de novo heart transplantation conducted at the same center. Total survival rates after heart transplantation were 43.5% for TAH-t BTT, 60% for BVAD BTT, 61.1% for LVAD BTT, and 60% for de novo heart transplants; however, the highest mortality rates for TAH-t BTT happened within one year post heart transplant, of those that survived the first year the survival rates were not significantly different

from all other post-transplant survival rates. The authors offered possible reasons for the significant difference in the first year mortality of TAH-t BTT patients including significantly increased adhesions due to the device, prolonged surgical preparation times leading to prolonged cold and warm ischemic times, and the inability to completely evaluate SynCardia TAH patients for transplantation due to the device not allowing for certain measurements such as pulmonary artery pressures and such, thus possibly covering up underlying significant vascular disease prior to transplantation. All these potential factors kept in mind; the authors concluded that TAH-t BTT is a viable option for patients when vigorous risk assessments are made on a case-by-case basis.

National and Specialty Organizations

The **American Association for Thoracic Surgery/International Society for Heart and Lung Transplantation** guidelines (Kirklin et al. 2020) note for patients with advanced biventricular failure who are transplant candidates can be considered for biventricular support or TAH. Patients who received an LVAD as bridge to transplant and remain with poorly controlled right ventricular failure (with or without a temporary right VAD) should be considered for longer-term biventricular support or TAH before end-organ dysfunction ensues.

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology)

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)
33929	Removal of a total replacement heart system (artificial heart) for heart transplantation (list separately in addition to code for primary procedure)

HCPCS (Healthcare Common Procedure Coding System)

Code	Description
L8698	Miscellaneous component, supply, or accessory for use with total artificial heart system

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

10/08/2025	Policy revised to include the 50cc device. Removed absolute contraindication of chest cavity measurements that were associated with the 70cc device. IRO peer review on September 16, 2025, by a practicing physician board certified in Cardiovascular Disease.
10/09/2024	Policy reviewed, no changes to coverage criteria. Updated Summary of Medical Evidence and References.
06/12/2024	Coverage criteria revised with removal of general transplant evaluation, continuation of therapy, and general contraindication coverage criteria as it is now stipulated in MCP 459 Pre-Transplant and Transplant Evaluation. Annual Review scheduled for October 2024.
10/12/2023	Policy reviewed, changes to criteria include age for colonoscopy reduced to 45 years, addition of non-life limiting neurological impairment criteria, removal of abnormal serology criteria and cannabis use section, and addition of active pregnancy and substance abuse statement to absolute contraindications. Overview, Summary of Medical Evidence, and References sections updated. IRO peer reviewed by a practicing physician board certified in cardiology August 2023.
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.
09/16/2020	Policy reviewed, no changes to criteria, updated references.
09/18/2019	Policy reviewed, no changes to criteria, updated references.
03/08/2018	Updated exclusions to include the SynCardia TAH-t System for permanent use as destination therapy; professional guidelines and references updated.
06/22/2017	Policy reviewed, no changes to criteria, updated references.
09/15/2016	Policy reviewed, no changes to criteria, updated references.
12/16/2015	Policy reviewed, no changes to criteria, updated references.
04/06/2015	New policy.

REFERENCES

1. 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. doi: 10.1016/j.healun.2020.11.012. PMID: 33341359.
2. Chen Q, Chan J, Akhmerov A, et al. Heart transplantation after total artificial heart bridging-Outcomes over 15 years. Clin Transplant. 2022 Nov;36(11): e14781. doi: 10.1111/ctr.14781. PMID: 35844069; PMCID: PMC9771925.
3. Feldman D, Pamboukian SV, Teuteberg JJ, 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.
4. Itagaki S, Toyoda N, Egorova N, et al. Total artificial heart implantation as a bridge to transplantation in the United States. J Thorac Cardiovasc Surg. 2022 Apr 9: S0022-5223(22)00385-3. doi: 10.1016/j.jtcvs.2022.02.058. PMID: 35618532.
5. 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 Thorac Cardiovasc Surg. 2020 Mar;159(3):865-896. doi: 10.1016/j.jtcvs.2019.12.021.
6. Mancini, D, Anyanwu A. Emergency care of adults with mechanical circulatory support devices. Updated January 17, 2024. Accessed September 15, 2025. https://www.uptodate.com
7. Melaragno JI, Bowman LJ, Park JM, et al. The Clinical Conundrum of Cannabis: Current Practices and Recommendations for Transplant Clinicians: An Opinion of the Immunology/Transplantation PRN of the American College of Clinical Pharmacy. Transplantation. 2021 Feb 1;105(2):291-299. doi: 10.1097/TP.0000000000003309. PMID: 32413017.
8. Morshuis M, Rojas SV, Hakim-Meibodi K, et al. Heart transplantation after SynCardia® total artificial heart implantation. Ann Cardiothorac Surg. 2020 Mar;9(2):98-103. doi: 10.21037/acs.2020.03.12. PMID: 32309157; PMCID: PMC7160625.
9. Razumov A, Burri M, Zittermann A, et al. Outcomes after SynCardia® temporary total artificial heart implantation: A 20-year single-center experience in 196 patients. Artif Organs. 2024 Sep 16. doi: 10.1111/aor.14860. Epub ahead of print. PMID: 39283166.
10. Senage T, David CH, Nanjaiah P, Roussel JC. Total artificial heart: patient selection and risk factors. Ann Cardiothorac Surg. 2020 Mar;9(2):118-120. doi: 10.21037/acs.2020.02.10. PMID: 32309162; PMCID: PMC7160622.
11. United States Food and Drug Administration (FDA). Pre-market approval (PMA): Syncardia artificial heart (multiple approvals). Product code LOZ. FDA.gov. Accessed September 15, 2025.
12. Villa CR, Moore RA, Morales DL, et al. The total artificial heart in pediatrics: Outcomes in an evolving field. Ann Cardiothorac Surg. 2020 Mar;9(2):104-109. doi: 10.21037/acs.2020.02.15. PMID: 32309158; PMCID: PMC7160627
13. Yancy CW, Drazner MH, Coffin ST, 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.
14. 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. doi/pdf/10.1016/j.jacc.2017.04.025.

APPENDIX

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

This policy contains prior authorization requirements.