Subject: Heart Transplantation with a Total Artificial Heart (TAH)		Original Effective Date: 4/6/15
Policy Number: MCP-245	**Revision Date(s):** 3/8/18	
Review Date: 12/16/15, 9/15/16, 6/22/17, 3/8/18, 9/18/19, 9/16/20		
MCPC Approval Date: 3/8/18, 9/18/19, 9/16/20		

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. 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 (i.e., 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 Molina Clinical Policy (MCP) document and provide the directive for all Medicare members.[1]

Contents

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL [2-4]

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.

There are two devices that are FDA approved:

1. The SynCardia temporary Total Artificial Heart TAH-t (SynCardia Systems, Inc., Tucson, AZ) formerly referred to as the CardioWest™ Total Artificial Heart**,** received FDA premarket approval (PMA) on October 15, 2004 as 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. Recently, the SynCardia Freedom® Driver System received FDA approval as a supplement to the original PMA on June 26, 2014. The device as modified is marketed under the trade name SynCardia temporary Total Artificial Heart with the Freedom Driver System, and 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. [3-4]

2. The AbioCor***** Implantable Replacement Heart System (ABIOMED, Inc., Danvers, MA) [2] 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. On September 5, 2006 the FDA approved the AbioCor device under the Humanitarian Use Device (HUD) provisions of the Food, Drug and Cosmetic Act. The Center for Devices and Radiological Health (CDRH) of the FDA approved the AbioCor Implantable Replacement Heart System (ABIOMED, Inc. Danvers, Mass) for use in severe biventricular end-stage heart disease individuals who are not cardiac transplant candidates.

***Note:** Although approved by the FDA in September 2006, the AbioCor is no longer being manufactured.*

RECOMMENDATION [3-26 27-29]

The Syncardia CardioWest™ temporary Total Artificial Heart (TAH-t) 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: [ALL]

- ❑ Must be used in accordance with FDA approval; and
- ❑ Eligible and listed for donor organ heart transplantation and meet all of the heart transplant criteria in MCP-116; and
- ❑ In imminent danger of dying within 48 hours or becoming ineligible for transplant; and
- ❑ New York Heart Association Functional Class IV; and
- ❑ Diagnosis of biventricular failure and rapid decompensation; and

- ❑ Unavailability of heart donor and likelihood that condition will deteriorate before donor can be identified; and
- ❑ None of the following contraindications to artificial heart transplantation are present:
  - Ineligible for donor heart transplant; or
  - 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.; or
  - Inability to be adequately anticoagulated on the CardioWest TAH-t

LIMITATIONS

- ❑ The AbioCor® Implantable Replacement Heart System is considered experimental, investigational and unproven for permanent use as destination therapy and any other indication.
- ❑ The SynCardia TAH-t System is considered experimental, investigational and unproven for permanent use as destination therapy.

SUMMARY OF MEDICAL EVIDENCE [5-26]

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. A summary of the most relevant studies is outlined below. [5-20]

Copeland et al. 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 ($P<0.001$). 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 ($P<0.001$). 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. 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 (all $p > 0.168$), but TAH was associated with reduced graft survival compared with LVADs ($p < 0.001$). 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 (all $p < 0.05$). 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.

Destination Therapy

There is very limited published evidence that show that the AbioCor TAH is a safe and efficacious permanent replacement for the failing heart (destination therapy) in carefully selected patients. Eligible patients include those with biventricular failure who have a less than 30-day predicted survival and no other viable treatment options (including heart transplantation). Therefore, the evidence is insufficient to support the use of the total artificial heart when used for destination therapy. [21-23]

CODING INFORMATION THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

CPT	Description:
0051T	Implantation of a total replacement heart system (artificial heart) with recipient cardiectomy *Deleted code effective 1/1/2018*
0052T	Replacement or repair of thoracic unit of a total replacement heart system (artificial heart) *Deleted code effective 1/1/2018*
0053T	Replacement or repair of implantable component or components of total replacement heart system (artificial heart), excluding thoracic unit *Deleted code effective 1/1/2018*
33927	Implantation of a total replacement heart system (artificial heart) with recipient cardiectomy *New code effective 1/1/2018*
33928	Removal and replacement of total replacement heart system (artificial heart) *New code effective 1/1/2018*
33929	Removal of a total replacement heart system (artificial heart) for heart transplantation (List separately in addition to code for primary procedure) *New code effective 1/1/2018*

HCPCS	Description
	N/A

ICD-10	Description: [For dates of service on or after 10/01/2015]
I50-I50.9	Heart Failure

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Professional Society Guidelines

27. ACCF/AHA Guidelines:

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28. ISHLT:
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    - Kirkland J, et al. American Association for Thoracic Surgery/International Society for Heart and Lung Transplantation guidelines on selected topics in mechanical circulatory support. J Heart Lung Transplant. 2020 March 1,Volume 39, ISSUE 3, P187-219.

Hayes & Other Resources

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    - Health Technology Assessment. Total Artificial Heart, Temporary or Permanent, Biventricular Mechanical Circulatory Support Device. Winifred Hayes Inc. Lansdale, Pa. May 28, 2015. Updated June, 2019. [archived 2020]
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    - Evidence Analysis. SynCardia Total Artificial Heart with the Freedom Portable Driver (Syncardia Systems Inc.) for Bridge to Transplantation in Children. Winifred Hayes Inc. Lansdale, Pa. Dec, 2014.
30. UpToDate: Waltham, MA. Walters Kluwer Health; 2020. Birks EJ. Intermediate- and long-term mechanical circulatory support.
31. AMR Review: Policy was reviewed by a physician board certified in Internal Medicine, Cardiovascular Disease, and Critical Care, 1/18/18.

Revision/Review History:

4/6/15: New Policy

12/16/15, 9/15/16 & 6/22/17: Policy reviewed, no changes
3/8/18: Updated exclusions section to include that the SynCardia TAH-t System is considered experimental, investigational and unproven for permanent use as destination therapy. Professional guidelines and reference sections were updated.
9/18/19 & 9/16/20: Policy reviewed, no changes. Updated references and added TOC.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this Molina Clinical Policy (MCP) document and provide the directive for all Medicare members.

There is a National Coverage Determination (NCD) for Artificial Hearts and Related Devices (20.9) that 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. [1]