MEDICAL POLICY

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MEDICAL POLICY DETAILS	
Medical Policy Title	**Artificial Hearts**
Policy Number	**7.01.65**
Category	**Technology Assessment**
Original Effective Date	**12/16/04**
Committee Approval Date	**10/20/05, 08/17/06, 06/21/07, 05/14/08, 05/28/09, 05/27/10, 05/19/11, 05/24/12, 06/20/13, 05/22/14, 06/18/15, 06/16/16, 06/15/17, 06/21/18, 06/20/19, 06/18/20, 06/17/21, 06/16/22, 06/22/23, 06/20/24**
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Product Disclaimer	• *Services are contract dependent; if a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP)* product) *covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.*

POLICY STATEMENT

I. Based upon our criteria and assessment of the peer-reviewed literature, the use of an FDA-approved total artificial heart is considered **medically appropriate** as a "bridge to transplant" for people with biventricular failure who meet **ALL** of the following criteria:
   A. No other reasonable medical or surgical treatment options are available;
   B. Ineligible for other univentricular or biventricular support devices;
   C. Currently listed as a heart transplantation candidate or undergoing evaluation to determine candidacy for heart transplantation;
   D. At risk of imminent death from non-reversible biventricular heart failure until a donor heart can be obtained.

II. Based upon our criteria and assessment of the peer-reviewed literature, the use of total artificial hearts as a permanent replacement for a human heart (destination therapy) is considered **investigational**.

Refer to Corporate Medical Policy #7.01.07 Ventricular Assist Devices

Refer to Corporate Medical Policy #7.02.06 Heart and Heart/Lung Transplant

Refer to Corporate Medical Policy #11.01.03 Experimental or Investigational Services

DESCRIPTION

Although cardiac transplantation is currently the only proven curative treatment for end-stage heart disease, the supply of donor hearts has not kept pace with the demand. Of the patients with end-stage cardiomyopathy on a heart transplant list, 95% do not receive a donor heart. Many other patients are not eligible for transplant. Therefore, artificial hearts as a means to maintain heart function or to provide a bridge to heart transplantation have been developed. One total artificial heart (TAH) currently being used is the SynCardia temporary-TAH (SynCardia, Tucson, AZ); another is the AbioCor

Implantable Replacement Heart (Abiomed, Danvers, MA). A TAH provides an option to patients in whom a left ventricular assist device (LVAD) or biventricular assist device may be contraindicated, including those with aortic regurgitation, cardiac arrhythmias, a left ventricular thrombus, an aortic prosthesis, an acquired ventricular septal defect, or an irreversible biventricular failure requiring high pump outputs.

The SynCardia t-TAH is a biventricular, pneumatic, pulsatile pump that serves as a total replacement for both ventricles of a heart. The SynCardia heart completely replaces the patient's native ventricles and all four cardiac valves. The TAH is connected to a console, via two pneumatic drivelines that exit the patient through the skin under the left costal margin. The console regulates heart rate, systolic duration, and driveline pressures for each of the two ventricles. The SynCardia t-TAH is intended as a temporary bridge to transplant and is removed at the time of transplantation. It is not intended for permanent use as a mechanical circulatory support system.

The AbioCor Implantable Replacement Heart is a totally implanted artificial heart intended for people who are not eligible for a heart transplant and who are unlikely to live more than a month without intervention. The AbioCor system consists of a two pound mechanical heart that takes over the pumping function of the diseased heart, which is removed during the implantation procedure; a power transfer coil that powers the system across the skin and recharges the internal battery from the outside; and a controller and an internal battery, which are implanted in the patient's abdomen. To receive the artificial heart, in addition to meeting other criteria, patients must undergo a screening process to determine if their chest volume is large enough to hold the device. The current, approved device is too large for about 90% of women and for many men. The AbioCor Implantable Replacement Heart is no longer being marketed or in development.

Several new total artificial heart devices are in early stages of development/trial to include the ReinHeart total artificial heart (ReinHeart TAH GmbH/Germany) and the AESON total artificial heart (CARMAT/Vélizy-Villacoublay, France).

RATIONALE

In October 2004, the FDA announced approval of the SynCardia Temporary-Total Artificial Heart (CardioWest Total Artificial Heart) (Syncardia) as a "bridge to transplant" for people who are eligible and waiting for a heart transplant, do not respond to other treatments, and are at risk of imminent death from non-reversible, biventricular failure. FDA approval of the Syncardia device was based on a review of clinical studies of safety and effectiveness conducted by the firm and on the recommendation of an outside panel of experts convened by the FDA to review the device. The required Syncardia to conduct a post-approval study to monitor the device's performance in commercial use. Several published clinical trials concluded that the SynCardia t-TAH is relatively safe and effective as a "bridge to transplant" in carefully selected heart transplant candidates.

On June 26, 2014, the FDA approved the SynCardia Freedom Driver System, which is a backpack-sized, portable device that connects to and supports the implanted TAH by a flexible pneumatic driveline. The SynCardia temporary Total Artificial Heart with the Freedom Driver System is indicated for use as a bridge to transplantation in cardiac transplant candidates who are clinically stable. The SynCardia Freedom Driver System is powered by two onboard batteries, which can be recharged using a standard electrical outlet or car charger. This portable technology device supports the temporary total artificial heart and enables the patient to leave the hospital and return to living at home.

On September 5, 2006, the FDA approved, under the Humanitarian Use Device (HUD) provisions of the Food, Drug and Cosmetic Act, the first totally implanted artificial heart for patients with advanced heart failure involving both pumping chambers of the heart. The AbioCor Implantable Replacement Heart, made by Abiomed, Inc. (Danvers, Mass.), is intended for people who are not eligible for a heart transplant and who are unlikely to live more than a month without intervention. The FDA indicated that its decision was based on Abiomed, Inc.'s laboratory and animal testing and on a small clinical study of 14 patients conducted by the company. The 14 patients had a one-month survival prognosis of not more than 30%, were not eligible for cardiac transplants, and were deemed unlikely to benefit from destination ventricular assist device (VAD) therapy. The study was reported to show that the device is safe and has likely benefit for people with severe heart failure whose death is imminent and for whom no alternative treatments are available. Of the 14 patients in the study, 12 survived surgeries. Mean duration of support for the patients was 5.3 months. In some cases, the device extended survival by several months; survival was 17 months in one patient. Six patients were ambulatory; one patient was discharged home. Complications included post-operative bleeding and neurological events. Device-related infection

was "non-existent." The FDA requires Abiomed to provide a comprehensive patient information package to patients and families that clearly describes the risks as well as the probable benefits of the device and explains what patients should expect before, during, and after surgery. To further refine and improve the use of this artificial heart technology, Abiomed was approved to conduct a post-marketing study but only few cases were reported, and the CE mark was not pursued. The post-market study was recommended by the Circulatory Systems Devices Panel, a part of the FDA's Medical Devices Advisory Committee. Additional clinical trials with relevant patient outcomes (complications, quality of life, survival, etc.) were further studied and analyzed resulting in the AbioCor Implantable Replacement Heart no longer being marketed. Therefore, based on current information, this device is considered investigational.

The American Heart Association, American College of Cardiology, and Heart Failure Society of America 2022 clinical practice guideline for the management of heart failure (Heidenreich, 2022) does not specifically address TAH but does provide recommendations regarding mechanical circulatory support (MCS). MCS is a therapeutic option for patients with advanced heart failure with reduced ejection fraction (HFrEF) to prolong life and improve functional capacity. Over the past 10 years, evolution and refinement of temporary and durable options has continued. Temporary MCS can help stabilize patients and allow time for decisions about the appropriateness of transitions to definitive management, such as durable MCS as a bridge or destination therapy, stabilization until cardiac transplantation or, in the case of improvement and recovery, suitability for device removal. These patients often present in cardiogenic shock that cannot be managed solely with IV inotropes and in whom other organ function is at risk. Temporary MCS is also appropriate for use to allow patients to engage in decision-making for durable MCS or transplantation and for determination of recovery of neurologic status. Particularly with temporary devices, the potential need to either discontinue or to escalate support should be addressed at time of implantation.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

CPT Codes

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 Codes

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

ICD10 Codes

Code	Description
I09.81	Rheumatic heart failure
I11.0	Hypertensive heart disease with heart failure

Code	Description
I13.0	Hypertensive heart and chronic kidney disease with heart failure and stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease
I13.2	Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease, or end stage renal disease
I50.20-I50.9	Heart failure, systolic and diastolic (congestive) (code range)

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*Key Article

KEY WORDS

AbioCor, Bridge to heart transplant, CardioWest, Destination therapy, SynCardia, TAH.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based on our review, Artificial Heart Devices are not addressed in National or Regional Medicare coverage determinations or policies.