

MEDICAL POLICY

SUBJECT: ARTIFICIAL HEARTS	EFFECTIVE DATE: 12/16/04
POLICY NUMBER: 7.01.65	REVISED 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
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<ul style="list-style-type: none">• <i>If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.</i>• <i>If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.</i>• <i>If a Medicare 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.</i>	

POLICY STATEMENT:

- I. Based upon our criteria and assessment of peer-reviewed literature, use of FDA approved total artificial hearts is considered **medically appropriate** as a “bridge to transplant” for people waiting for a heart transplant who do not respond to other treatments and are at risk of imminent death from non-reversible bi-ventricular failure, and who are listed as heart transplant candidates.
- II. Based upon our criteria and assessment of peer-reviewed literature, 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 regarding Ventricular Assist Devices.

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

Refer to Corporate Medical Policy #11.01.03 regarding Experimental and Investigational Services.

POLICY GUIDELINES:

The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

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. Two total artificial hearts (TAH) currently being used are the SynCardia temporary-TAH (SynCardia, Tucson, AZ) and the AbioCor Implantable Replacement Heart (Abiomed, Danvers, MA). TAH provides an option to patients in whom LVAD and biventricular assist devices may be contraindicated, including those with aortic regurgitation, cardiac arrhythmias, a left ventricular thrombus, an aortic prosthesis, an acquired ventricular septal defect, or 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 although the development of a portable driver (currently used in Europe) makes it possible that this device could be used for destination therapy.

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 2-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.

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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.

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 waiting for a heart transplant who do not respond to other treatments and are at risk of imminent death from non-reversible bi-ventricular failure, and who are eligible for a heart transplant. 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 FDA to review the device. FDA is requiring the firm 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 September 5, 2006, the FDA approved the first totally implanted artificial heart for patients with advanced heart failure involving both pumping chambers of the heart under the Humanitarian Use Device (HUD) provisions of the Food, Drug and Cosmetic Act. 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 their decision was based on the company's laboratory and animal testing and on a small clinical study of 14 patients conducted by Abiomed. The patients had a one-month survival prognosis of not more than 30%, were not eligible for cardiac transplants, and were felt to not benefit from destination VAD (ventricular assist device) 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 surgery. 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 is requiring 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 will conduct a post-marketing study of 25 additional patients. The post-market study was recommended by the Circulatory Systems Devices Panel, a part of the FDA's Medical Devices Advisory Committee.

This device shows technological progress and these initial results are encouraging; however, a number of questions remain. These questions may be answered once the results of the 14-patient study are published or data on a larger group of patients may be needed. One issue is to further analyze relevant patient outcomes (complications, quality of life, survival, etc.). Therefore, based on current information, this device is considered investigational.

CODES: Number Description

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.

<u>CPT:</u>	33927	Implantation of total replacement heart system (artificial heart) with recipient cardiectomy (<i>effective 1/1/2018</i>)
	33928	Removal and replacement of total replacement heart system (artificial heart) (<i>effective 1/1/2018</i>)
	33929	Removal of total replacement heart system (artificial heart) for heart transplantation (list

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separately in addition to code for primary procedure) (*effective 1/1/2018*)

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HCPCS: No codes

ICD10: I09.81 Rheumatic heart failure
I11.0 Hypertensive heart disease with heart failure
I130 Hypertensive heart and chronic kidney disease with heart failure and stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease
I132 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, TAH.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) for Artificial Hearts and Related Devices. Please refer to the following NCD website for Medicare Members: <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=246&ncdver=6&bc=AgAAgAAAAAAAAAAA%3d%3d&>.