National Medical Policy

Subject: **Total Artificial Heart**

Policy Number: **NMP188**

Effective Date*: **November 2004**

Updated: **September 2015**

This National Medical Policy is subject to the terms in the IMPORTANT NOTICE at the end of this document

For Medicaid Plans: Please refer to the appropriate Medicaid Manuals for coverage guidelines prior to applying Health Net Medical Policies

The Centers for Medicare & Medicaid Services (CMS)
For Medicare Advantage members please refer to the following for coverage guidelines first:

Use	Source	Reference/Website Link
X	National Coverage Determination (NCD)	Artificial Hearts and Related Devices (20.9): http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx
	National Coverage Manual Citation	
	Local Coverage Determination (LCD)*	
	Article (Local)*	
X	Other	MLN Matters. MM6185. - Medicare Coverage of Artificial Hearts http://www.cms.gov/mlnmattersarticles/downloads/MM6185.pdf MLN Matters Number: MM7134 Revised October 1, 2010. Medicare Coverage of Artificial Hearts: http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM7134.pdf MLN Matters. MM6634 Revised September 17, 2009. Updated January 3, 2013. Fiscal Year (FY) 2010 Inpatient Prospective Payment System (IPPS): http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM6634.pdf

		CMS. Decision Memo for Ventricular Assist Devices as Destination Therapy: http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=243&ver=9&NcaName=Ventricular+Assist+Devices+as+Destination+Therapy+(2nd+Recon)&bc=BEAAAAAAEAAA&&fromdb=true
	None	Use Health Net Policy

Instructions

- Medicare NCDs and National Coverage Manuals apply to ALL Medicare members in ALL regions.
- Medicare LCDs and Articles apply to members in specific regions. To access your specific region, select the link provided under "Reference/Website" and follow the search instructions. Enter the topic and your specific state to find the coverage determinations for your region. *Note: Health Net must follow local coverage determinations (LCDs) of Medicare Administration Contractors (MACs) located outside their service area when those MACs have exclusive coverage of an item or service. (CMS Manual Chapter 4 Section 90.2)
- If more than one source is checked, you need to access all sources as, on occasion, an LCD or article contains additional coverage information than contained in the NCD or National Coverage Manual.
- If there is no NCD, National Coverage Manual or region specific LCD/Article, follow the Health Net Hierarchy of Medical Resources for guidance.

Current Policy Statement

I. Total Artificial Heart

Health Net, Inc. considers the temporary use of an FDA approved total artificial heart (e.g., Cardio West Total Artificial Heart [TAH], now referred to as Syncardia temporary CardioWest Total Artificial Heart (TAH-t), medically necessary as a bridge to heart transplantation for a select group of patients who meet **all** of the following criteria:

1. Patient is approved for cardiac transplant and is currently on transplant list
2. New York Heart Association (NYHA) Functional Class IV
3. Presence of nonreversible biventricular failure unresponsive to all other treatments
4. Ineligible for other ventricular support devices
5. Compatible donor heart is unavailable at the moment
6. Imminent risk of death
7. Sufficient space in the chest area vacated by the natural ventricles (generally body surface areas greater than 1.7 m2 and a distance between the sternum and the 10th anterior vertebral body measured by computed tomography imaging greater than or equal to 10cm) to support the TAH
8. Patient is able to receive adequate anti-coagulation while on the total artificial heart.

Investigational

Health Net, Inc. considers the Total Artificial Heart investigational in either of the following situations, since there is a paucity on the safety and efficacy of this device in these specific scenarios:

- For the use of this device as destination therapy in individuals who are not transplant candidates; OR
- For the hospital discharge of patients implanted with the Total Artificial Heart who are supported by portable drivers, and are not transplant candidates (e.g., the Freedom portable driver).

II. AbioCor Implantable Replacement Heart

Health Net Inc. considers the AbioCor Implantable Replacement Heart (Abiomed Inc.) medically necessary when provided in accordance with the Humanitarian Device Exemption (HDE) specifications of the U.S. Food and Drug Administration (FDA).

Per the FDA, the AbioCor Implantable Replacement Heart is indicated for use in patients with severe biventricular end stage heart disease who meet all the following criteria:

1. Are less than 75 years old
2. Are not transplant candidates at the time of assessment
3. Require multiple inotropic support
4. Are in biventricular failure not treatable by left ventricular assist devices (LVAD) destination therapy*
5. Are not weanable from temporary biventricular support if on such support and not awaiting transplantation

*Destination therapy (long term/permanent placement) refers to the use of ventricular assist devices (VADs) as a permanent implant and an alternative to cardiac transplantation.

Note: The device is large and this limits its use in smaller patients (i.e. women, small men and children). Per the FDA, in order to receive the artificial heart, in addition to meeting the above criteria, patients must undergo a pre-assessment of the anatomic fit of the AbioCor prior to surgical implantation of the device (i.e. a virtual surgery program which placed the AbioCor in the chest using the internal chest dimensions from MRI or CT scans). The criteria for good fit includes proper alignment of the inflows with the mitral and tricuspid valve planes without compression of the atria, of the right outflow, or the pulmonary artery; non-interference with the descending aorta and the pulmonary veins; device remains completely within the rib cage and adequate atrial volume.

Per the FDA, the AbioCor Implantable Replacement Heart is contraindicated in patients with any of the following:

1. Other irreversible end organ functions that would compromise survival
2. Inadequate psychosocial support
3. Preoperative noninvasive anatomical assessment indicating inadequate fit (i.e.thoracic volume is unable to accommodate the device)

4. Presence of coagulation disorders

Codes Related To This Policy

NOTE:
The codes listed in this policy are for reference purposes only. Listing of a code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the benefit documents and medical necessity criteria. This list of codes may not be all inclusive.

On October 1, 2015, the ICD-9 code sets used to report medical diagnoses and inpatient procedures will be replaced by ICD-10 code sets. Health Net National Medical Policies will now include the preliminary ICD-10 codes in preparation for this transition. Please note that these may not be the final versions of the codes and that will not be accepted for billing or payment purposes until the October 1, 2015 implementation date.

ICD-9 Codes

428.1	Left heart failure
428.9	Heart failure, unspecified

ICD-10 Codes

I50.1	Left ventricular failure
I5Ø.9	Heart failure, unspecified

CPT Codes

0051T	Implantation of a total replacement heart system (artificial heart) with recipient cardiectomy
0052T	Replacement or repair of thoracic unit of a total replacement heart system (artificial heart)
0053T	Replacement or repair of implantable component or components of total replacement heart system (artificial heart), exclusing thoracic unit

HCPCS Codes

N/A

Scientific Rationale – Update September 2015

The FDA granted marketing approval for the Freedom driver system on June 26, 2014, in a supplement to the original PMA application (P030011). The system is indicated for use as a bridge to transplantation in cardiac transplant candidates who have been implanted with the SynCardia device and are clinically stable.

There was a PMA approval of P030011/S029, for the SynCardia Temporary Total Artificial Heart (TAH-t) System on September 29, 2014. A manufacturing transfer of various injection molded parts belonging to the Freedom Driver to a new supplier, was accomplished. The Freedom portable driver is the wearable power supply for the SynCardia Total Artificial Heart.

In 2014, the American College of Cardiology (ACC) and the American Heart Association (AHA) invited the Heart Failure Society of America (HFSA) to be a full

partner in the development of the next revision of the Guideline for the Management of Heart Failure. It will be titled the ACC/AHA/HFSA Guideline for the Management of Heart Failure.

Per a CMS Decision Memo on Ventricular Assist Devices (VAD), The evidence is adequate to conclude that VAD implantation as destination therapy improves health outcomes and is reasonable and necessary when the device has received FDA approval for a destination therapy indication and only for patients with New York Heart Association (NYHA) Class IV end-stage ventricular heart failure who are **not** candidates for heart transplant and who meet all of the following conditions:

- Have failed to respond to optimal medical management (including beta-blockers, and ACE inhibitors if tolerated) for at least 45 of the last 60 days, or have been balloon pump dependent for 7 days, or IV inotrope dependent for 14 days; and,
- Have a left ventricular ejection fraction (LVEF) < 25%; and,
- Have demonstrated functional limitation with a peak oxygen consumption of ≤ 14 ml/kg/min unless balloon pump or inotrope dependent or physically unable to perform the test.

Scientific Rationale – Update September 2014

Gurudevan et al. (2014) examined the clinical outcomes of 22 patients with end-stage NYHA Class IV heart failure who were referred for cardiac transplantation and underwent surgical implantation of the Syncardia total artificial heart (TAH) as a bridge to transplantation. All patients had pre-operative transthoracic echocardiography. Clinical outcomes, including death, and the incidence of stroke 60 days post–TAH implantation was evaluated in all patients. Of 22 patients studies, all had end-stage cardiomyopathy with mean LV end diastolic dimension of 60, 18 mm and a mean LV ejection faction of 24, 13% on preoperative transthoracic echocardiography. Right ventricular function was normal in 5 patients, mildly depressed in 9 patients, moderately depressed in 2 patients, and severely depressed in 6 patients. There were a total of 7 deaths (32%), 5 (23%) of which occurred within 60 days. Three patients (14%) had CVAs and 5 patients successfully underwent cardiac transplantation, while the remaining 10 are alive and awaiting a donor organ. 8 patients were discharged home with a portable drive line (The Freedom Driver). There were no TAH infections in the population studied. This is the largest single center series of patients treated with the total artificial heart that has been reported to date. This data demonstrates that the total artificial heart is a very good efficacious tool to bridge end-stage heart failure patients to cardiac transplantation. It also notes the discharge of patients home to await transplant.

Scientific Rationale – Update September 2013

Biventricular support can be achieved using paracorporeal biventricular assist devices (BiVADs), the total artificial heart (TAH), and implantable VADs.

Kirsch et al. (2012) completed a study that evaluated the influence of the device on patient survival. Data from 383 patients (321 men [84%]) undergoing primary, planned biventricular support using durable devices between 2000 and 2010 were used. Mean age was 41.6±14.0 years. Patients were classified as group 1, 255 (67%) with paracorporeal BiVADs; group 2, 90 (24%) with TAH; and group 3, 38 (10%) with implantable BiVADs. Mean patient support duration was 82.8±107.4 days and similar among groups ($p = 0.53$). Bridging to transplantation was successful in 211 patients (55%) and to recovery in 23 (6%). Mortality on device

was similar among groups (p = 0.16). TAH patients had a significantly lower stroke rate (p<0.0001). Actuarial estimates for survival while on support were 75.2%±2.3%, 64.4%±2.7%, 61.1%±2.8%, and 56.8%±3.1% at 30, 60, 90, and 180 days, respectively, and were similar among groups. However, TAH patients undergoing prolonged support (≥90 days) showed a trend toward improved survival (p = 0.08). Actuarial post-transplant survival estimates were, respectively, 81.7±2.7, 75.3±3.0, 73.0±3.0, and 64.7±3.7 at 1 month and 1, 3, and 5 years and were similar among groups (p = 0.84). Survival while on support and after heart transplantation did not differ significantly in patients supported with paracorporeal BiVADs, implantable BiVADs, or the TAH. Patients undergoing prolonged support (>90 days) tended to have improved survival when supported with TAH compared with BiVADs, which may be related to a lower incidence of neurologic events.

Scientific Rationale – Update September 2012

Copeland et al (2012) reported their experience with SynCardia Total Artificial Heart implantation documenting its indications, safety, and efficacy. Data regarding preoperative condition, mortality, and morbidity were reviewed and analyzed. From January 1993 to December 2009, 101 patients had bridge to transplant procedures with the SynCardia Total Artificial Heart. Ninety-one percent of cases were Interagency Registry for Mechanically Assisted Circulatory Support profile 1, and the remaining 9% of cases were failing medical therapy on multiple inotropic medications. The mean support time was 87 days (median, 53 days; range, 1-441 days). Pump outputs during support were 7 to 9 L/min. Adverse events included strokes in 7.9% of cases and take-back for hemorrhage in 24.7% of cases. Survival to transplantation was 68.3%. Causes of death of 32 patients on device support included multiple organ failure (13), pulmonary failure (6), and neurologic injury (4). Survival after transplantation at 1, 5, and 10 years was 76.8%, 60.5%, and 41.2%, respectively. The longest-term survivor is currently alive 16.4 years postimplantation. Reviewers concluded SynCardia Total Artificial Heart offers a real alternative for survival with a reasonable complication rate in appropriate candidates who otherwise might have been assigned to hospice care.

Scientific Rationale – Update February 2011

According to the manufacturer, SynCardia Systems Inc., "Pneumatic drivers have powered the Total Artificial Heart for close to 30 years. Because of its unique design, the Total Artificial Heart doesn't require sensors, motors or electronics of any type inside the body. All electronics for the Total Artificial Heart are safely located outside the body in the pneumatic driver. There is never a need to re-operate to repair faulty electronics. SynCardia implant drivers support patients from implant of the SynCardia temporary Total Artificial Heart until their condition stabilizes. In Europe, stable patients are then switched to a portable driver and discharged from the hospital. The new, wearable Freedom driver system has received the CE Mark for use in Europe. SynCardia is also conducting FDA-approved Investigational Device Exemption (IDE) clinical study of the Freedom driver in the U.S."

Smedira et al (2010) investigated the complex interplay of duration of mechanical circulatory support and patient and device factors affecting survival on support, as well as survival after transplantation. Mechanical circulatory support was used in 375 patients as a bridge to transplantation, with 262 surviving to transplant. Implantable pulsatile devices were used in 321 patients, continuous flow was used in 11 patients, a total artificial heart was used in 5 patients, external pulsatile devices were used in 34 patients, and extracorporeal membrane oxygenation was used in 68 patients. Two time-related models were developed: a competing-risks multivariable

model of death on mechanical circulatory support, with modulated renewal for each sequential support mode; and a model of death after transplant in which patient factors and duration of mechanical circulatory support were investigated as risk factors. Survival after initiating mechanical circulatory support, irrespective of transplantation, was 86% at 30 days, 55% at 5 years, and 41% at 10 years; survival was 94%, 74%, and 58% at the same time intervals, respectively, after transplantation in those surviving the procedure. Risk factors for death included longer, but not shorter, duration of mechanical circulatory support, use of multiple devices, global sensitization, and poor renal function. The investigators concluded initiating mechanical circulatory support early with a single definitive device may improve survival to and after cardiac transplantation. Early transplant, which avoids infection, sensitization, and neurologic complications, may improve bridge and transplant survival.

Platis et al (2009) reviewed the current literature and highlighted the chronology of the CardioWest temporary total artificial heart (TAH-t). The reviewers reported the CardioWest TAH-t has been implanted in over 715 patients at 30 multiple institutional centers worldwide as a bridge-to-transplant (BTT) since 1993. The mechanical flow dynamics of the device are manufactured and designed differently from other traditional VADs, allowing increased outputs and normal filling pressures, allowing for sufficient organ and tissue perfusion and dramatic recoveries, allowing patients to return to an almost normal quality of life. There was a 79% survival to transplant achievement in the protocol group who received the TAH-t versus a 46% in the control group ($P < 0.001$). There was a 70% survival rate at one year in the protocol group versus 31% in the control group ($P < 0.001$). The one- and five-year survival rates after transplantation were 69% and 34%, respectively, in the control group and 86% and 64%, respectively, in the protocol group.

In a single-center retrospective study, Roussel et al (2009) assessed both the comorbidity and survival of 42 patients awaiting heart transplants while receiving circulatory support with a CardioWest total artificial heart. Mean age at the time of implantation was 45.7 +/- 9.5 years, and 40 patients (95%) were men. Idiopathic or dilated cardiomyopathy was diagnosed in 45.2% (n = 19) of the patients and ischemic cardiomyopathy in 42.8% (n = 18). Average body surface area was 1.9 +/- 0.22 m(2). Duration of support was 1 to 292 days (mean, 101 +/- 86 days). Twelve patients died (28.5%) while receiving device support, and 30 patients (71.5%) underwent transplantation. Actuarial survival rates for the transplanted patients were 90% (n = 25), 81% (n = 14), and 76% (n = 10) at 1, 5, and 10 years, respectively. Causes of death during device support included multiorgan failure in 6 (50%), sepsis in 2, acute respiratory distress syndrome in 2, alveolar hemorrhage in 1, and other cause in 1. There were no device malfunctions that led to patient death. Adverse events included stroke in 3 patients (7%) and infections in 35 patients (85%) during support. The investigators concluded the CardioWest total artificial heart is an excellent bridge-to-transplant device for patients with biventricular failure. Our study demonstrates excellent safety, reliability, and efficiency. Exceptional outcome after transplantation underlines its capacity to aid in end-organ recovery.

Scientific Rationale - Update February 2009

Effective 12/2008, CMS will allow coverage for an artificial heart for bridge-to-transplantation or for destination therapy, when performed under coverage with evidence development (CED) when the clinical study meets specific Medicare criteria.

Scientific Rationale - Update February 2007

In September 2006, the U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH) approved the first totally implanted artificial heart under the Humanitarian Use Device (HUD) provisions of the Food, Drug and Cosmetic Act. Devices approved under the HUD provisions are those intended to treat conditions or diseases that affect fewer than 4,000 people a year in the United States. Similar to the Orphan Drug Act, the HUD provisions was designed to encourage development of innovative medical devices to treat rare conditions. It allows medical devices to be approved for market if they demonstrate safety and probable benefit.

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 AbioCor Implantable Replacement Heart, 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. The controller monitors and controls the functioning of the device, including the pumping rate of the heart. The internal battery allows the recipient to be free from all external connections for up to one hour. The system also includes two external batteries that allow free movement for up to two hours. During sleep and while batteries are being recharged, the system can be plugged into an electrical outlet.

The FDA based its approval on the Feasibility Study conducted by Abiomed, Inc. intended to assess the safety and probable benefit of the fully implantable AbioCor replacement heart. Fourteen patients with end-stage heart failure whose therapeutic options had been exhausted were included in the study. Candidates enrolled in the trial had a one-month survival prognosis of not more than 30%. Candidates were not transplant eligible and were those who could not benefit from destination LVAD support. The trial was initially designed to assess patient survival at two months. The incremental gate for trial continuation in each group of five patients was based on one of five patients surviving to 60 days. Twelve patients of the fourteen candidates survived surgery, representing an 86% success rate for a radically new procedure. Support duration of the twelve patients ranged from 53 to 512 days. The majority of the patients (71%) survived beyond the 60-day milestone set for one of five patients (20%). The mean duration of support for the supported patients was 5.3 months. The study showed 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. Six patients were ambulatory. Four patients have had excursions outside of the hospital, and two of these four patients were discharged to facilities near the hospital as intermediary steps toward final discharge to home. One of these two patients was discharged to home shortly thereafter.

To further refine and improve the use of this artificial heart technology, Abiomed will continue to do additional laboratory studies and will also 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 agency's Medical Devices Advisory Committee. The FDA is also requiring that Abiomed provide a comprehensive information package for patients and families that clearly describes the risks as well as the benefits of the device and explains what can be expected before, during and after surgery.

Per the manufacturer, the AbioCor will be made available through a controlled roll-out at approximately five to ten heart hospitals in the United States, including qualified clinical trial sites and additional qualified centers once they have completed a comprehensive and rigorous training program which may take six to eight months. The Jewish Hospital in Louisville, KY, an AbioCor clinical trial site, will be among the first U.S. hospitals to offer patients the AbioCor. At the time this policy was developed (2/2007), two other hospitals are entering into a letter of intent. They are: The Johns Hopkins Hospital in Baltimore, MD, and Robert Wood Johnson University Hospital in New Brunswick, NJ.

Scientific Rationale - Update April 2006

Heart transplantation has become the standard treatment for eligible patients with irreversible biventricular failure unresponsive to medical and surgical treatment. Several published uncontrolled and nonrandomized clinical trials conducted at heart transplantation centers have demonstrated that in patients with end-stage heart failure who have no other reasonable treatment options and who meet strict selection criteria, the CardioWest Total artificial heart (TAH) is a relatively safe and efficacious bridge to transplantation. The existing data are limited to studies performed at specific transplant centers under a strict protocol.

The AbioCor Implantable Replacement Heart (IRH) System (Abiomed) received an FDA Investigational Device Exemption (IDE) in 2001, but is not yet approved for use outside of the investigational setting. It is intended for permanent cardiac replacement. Abiomed requested FDA Humanitarian Device Exemption (HDE) status for the AbioCor TAH in 2004. In June 2005, the Circulatory System Devices Panel of the FDA narrowly rejected Abiomed's request for HDE status, expressing concern that patients might not live long enough and with a sufficiently good quality of life to justify the risks of complications, including stroke and severe bleeding. At that time, the device had been implanted in 14 patients who lived less than 5 months on average after the surgery (1 patient survived 17 months). Although the AbioCor IRH is a promising technology for patients with no other treatment options, there is insufficient evidence in the published medical literature to demonstrate the safety and efficacy of this device.

Scientific Rationale - Initial

With improved outcomes in both quality of life and percentage of patients surviving, cardiac transplantation has become accepted therapy for many patients with end-stage heart disease. The advances in medical management and immunosuppression have made this possible. The most frequent indications are equally divided between ischemic heart disease and cardiomyopathy. Although heart transplantation has proven the benefits of replacing a diseased heart with a healthy heart, the benefits of heart transplantation are limited by acute rejection of the transplanted heart; complications of the necessary immunosuppressive therapy, and the development of transplant coronary arteriopathy. A mechanical blood pump holds the potential of immediate availability, no need for immunosuppression, and lack of acute or chronic rejection.

Patients with a poor prognosis for 6-month survival, for a large group of patients with symptomatic cardiomyopathy and ominous objective findings (ejection fraction < 20%, stroke volume ≤40 ml, severe ventricular arrhythmias), timing may be somewhat difficult. In addition, the tendency to relax a fairly rigid selection process

to obtain excellent results in individual patients has resulted in an effort to extend the benefits of transplantation to a larger number of patients. This has heightened the problem of donor scarcity.

Each year approximately 4,000 Americans need heart transplants, but only about one half receive them. Unfortunately, organ donations don't keep pace with the demand. Consequently, many candidates succumb before reaping the benefits of transplantation. Patients in whom conventional medical therapy fails may require some temporary assistance to ensure they're still alive when the donor heart becomes available. Roughly 500 patients need either intra-aortic balloon counterpulsation or possibly a ventricular assist device (VAD) per year. More than 2000 ventricular assist devices have been implanted and 69% of intention-to-bridge patients go on to successful transplantation. Unfortunately, rigging double VADs in the most severe transplant candidates where optimal medical therapy has failed to improve biventricular heart failure and death is imminent within 30 days is difficult, to say the least.

On October 19, 2004, The Food and Drug Administration (FDA) approved usage of the first temporary artificial heart. The FDA said its approval of the heart device was based on a review of clinical studies of safety and effectiveness conducted by the firm (Syncardia Systems Inc., of Tucson, Arizona) and on the recommendation of an outside panel of experts convened by FDA to review the device. The device is called the CardioWest Total Artificial Heart (TAH) and it's not intended to replace the human heart, and it's not a permanent solution. Instead, this pulsating bi-ventricular device promises to be the first device to work by replacing, not just boosting, the ventricles and serves as a "bridge transplant", keeping hospitalized patients alive until donated hearts become available. It is estimated that about 100 of the 4,000 patients awaiting transplants have irreversible failure of the left and right ventricles and could be candidates for this new artificial heart. Even though this artificial heart is expected to be used rarely, it is hoped to support a very important niche for a small number of patients who have run out of other options.
The pivotal clinical trial involved 81 patients eligible for transplants at five medical centers. All the patients had severe bi-ventricular heart failure and were judged not to be candidates for VADs. Even though each recipient undergoes cardiectomy, the chest must be big enough for the somewhat bulky implant. The device would then be connected by tubes running through a patient's chest wall to a large power-generating console, which operates and monitors the device. After receiving the artificial heart, 79 percent of those patients remained alive long enough to receive a donor heart (an average of 79 days), demonstrating that it could successfully serve as a bridge to transplant. The average patient lived an additional 79 days, and the longest lived for 400 days before heart transplantation. Infection was the most common complication, affecting 72% of participants. Bleeding was seen in 42% of patients, while 25% suffered neurological events such as major or minor stroke. The device malfunctioned in 18% of patients cases mostly because of kinks in the generator's tubing temporarily cut power, and 17 patients died before a donor heart could be found. Ultimately, what convinced some FDA advisers was that some CardioWest recipients had liver and kidney damage clear up - potentially making them better transplant candidates.

Because the clinical trial enrolled so few people, the FDA is requiring the company to monitor an additional 50 patients for one year after they receive the implant. The FDA will said it will require to conduct a post-marketing study of the device to monitor the device's performance in commercial use.

Lending itself as a historical context, the Jarvik 7 artificial heart was implanted in seven people two decades ago and it was considered a success in the sense that it demonstrated such a device could keep patients alive. This experimentation was abandoned because patients were sustaining thrombotic complications manifested by strokes, bleeding complications, and infectious complications. The public's perception was that the Jarvik 7 artificial heart fell short in providing a minimally adequate quality of life, and, therefore was not entirely suitable for further study. The CardioWest total artificial heart is a direct descendent of the Jarvik heart.

Over time, more compact systems for outpatient management have developed, and the use of all of these devices as portable bridges to transplantation, to recovery, or as permanent replacement therapy has become a more real possibility. Since the new artificial heart is a temporary measure of last resort, the need for donated hearts remains as strong as ever.

Review History

November 9, 2004	Medical Advisory Council, initial approval
April 18, 2006	Policy revised to consider CardioWest TAH medically appropriate in a select group of patients with untreatable biventricular failure
February 2007	Policy revised to consider the AbioCor Implantable Replacement Heart medically appropriate when provided in accordance with the Humanitarian Device Exemption specifications of the U.S. Food and Drug Administration.
February 2009	Update – no revisions
February 2011	Update – no revisions
October 2011	Update - no revisions
September 2012	Update – no revisions
September 2013	Update – no revisions. Codes updated.
September 2014	Update – no revisions. Codes updated.
September 2015	Update – Added total artificial heart as investigational for individuals who are not transplant candidates, and may need destination therapy &/or are discharged from hospitals with Total Artificial Heart implanted, supported by portable drivers. Codes updated.

This policy is based on the following evidenced-based guidelines:

1. BlueCross BlueShield Association. Ventricular Assist Devices and Total Artifical Hearts. Medical Policy Reference Manual Policy #7.03.11. 2003 Oct 9.CMS Coverage Issues Manual. Heart transplants 35-87.
2. Hayes Medical Technology Directory. Total Artificial Heart, Temporary or Permanent Biventricular Support Device. July 18, 2005. Updated June 23, 2009. Archived 2010.
3. Department of Health and Human Services. Food & Drug Administration. Center of Device and Radiologic Health. Available at: http://www.fda.gov/ohrms/dockets/ac/05/briefing/2005-149b2_04_Abiomed%20FDA%20Summary%20-%20final.doc.
4. Hunt SA, Abraham WT, Chin MH, et al. American College of Cardiology Foundation; American Heart Association. 2009 Focused update incorporated into the ACC/AHA 2005 guidelines for the diagnosis and management of heart failure in adults: a report of the American College of Cardiology Foundation/American

Heart Association Task Force on practice guidelines developed in collaboration with the International Society for Heart and Lung Transplantation. J Am Coll Cardiol. Apr 14 2009; 53 (15):e1-e90. Available at: http://circ.ahajournals.org/content/119/14/e391.full.pdf
ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure 2008: the Task Force for the Diagnosis and Treatment of Acute and Chronic Heart Failure 2008 of the European Society of Cardiology. Developed in collaboration with the Heart Failure Association of the ESC (HFA) and endorsed by the European Society of Intensive Care Medicine (ESICM).
6. McMurray JJ, Adamopoulos S, Anker SD, et al. ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure 2012: The Task Force for the Diagnosis and Treatment of Acute and Chronic Heart Failure 2012 of the European Society of Cardiology. Developed in collaboration with the Heart Failure Association (HFA) of the ESC. Eur Heart J 2012; 33:17
7. Yancy CW, Jessup M, Bozkurt B, et al. 2013 ACCF/AHA Guideline for the Management of Heart Failure: Executive Summary: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. Circulation 2013.
8. Feldman D, Pamboukian SV, Teuteberg JJ, et al. The 2013 International Society for Heart and Lung Transplantation guidelines for mechanical circulatory support. J Heart Lung Transplant. 2013;32(2):1-146.
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2. El Banayosy A, Kizner L, Arusoglu L, et al. Home discharge and out-of-hospital follow-up of total artificial heart patients supported by a portable driver system. ASAIO J. 2014;60(2):148-153.
3. Heart Failure Society of America (HFSA). HFSA to be a Full Partner with the ACC and the AHA on Next Heart Failure Guidelines. April 22, 2014. Available at: http://www.hfsa.org/hfsa-wp/wp/hfsa-to-be-a-full-partner-with-the-acc-and-the-aha-on-next-heart-failure-guidelines/
4. Holley CT, Harvey L, John R. Left ventricular assist devices as a bridge to cardiac transplantation. J Thorac Dis. 2014;6(8):1110-1119.
5. Thanavaro KL, Tang DG, Kasirajan V, Shah KB. Clinical indications for implantation of the total artificial heart. ASAIO J. 2014;60(5):594-596.
6. U.S. FDA. June 2014 PMA Approvals. Application Number/ Date of approval. Freedom Driver. Available at: http://www.fda.gov/medicaldevices/productsandmedicalprocedures/deviceapprovalsandclearances/pmaapprovals/ucm412361.htm
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evidence-based guidelines of governmental bodies, and evidence-based guidelines and positions of select national health professional organizations. Coverage determinations are made on a case-by-case basis and are subject to all of the terms, conditions, limitations, and exclusions of the member's contract, including medical necessity requirements. Health Net may use the Policies to determine whether under the facts and circumstances of a particular case, the proposed procedure, drug, service or supply is medically necessary. The conclusion that a procedure, drug, service or supply is medically necessary does not constitute coverage. The member's contract defines which procedure, drug, service or supply is covered, excluded, limited, or subject to dollar caps. The policy provides for clearly written, reasonable and current criteria that have been approved by Health Net's National Medical Advisory Council (MAC). The clinical criteria and medical policies provide guidelines for determining the medical necessity criteria for specific procedures, equipment, and services. In order to be eligible, all services must be medically necessary and otherwise defined in the member's benefits contract as described this "Important Notice" disclaimer. In all cases, final benefit determinations are based on the applicable contract language. To the extent there are any conflicts between medical policy guidelines and applicable contract language, the contract language prevails. Medical policy is not intended to override the policy that defines the member's benefits, nor is it intended to dictate to providers how to practice medicine.

Policy Effective Date and Defined Terms.
The date of posting is not the effective date of the Policy. The Policy is effective as of the date determined by Health Net. All policies are subject to applicable legal and regulatory mandates and requirements for prior notification. If there is a discrepancy between the policy effective date and legal mandates and regulatory requirements, the requirements of law and regulation shall govern. * In some states, prior notice or posting on the website is required before a policy is deemed effective. For information regarding the effective dates of Policies, contact your provider representative. The Policies do not include definitions. All terms are defined by Health Net. For information regarding the definitions of terms used in the Policies, contact your provider representative.

Policy Amendment without Notice.
Health Net reserves the right to amend the Policies without notice to providers or Members. In some states, prior notice or website posting is required before an amendment is deemed effective.

No Medical Advice.
The Policies do not constitute medical advice. Health Net does not provide or recommend treatment to members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

No Authorization or Guarantee of Coverage.
The Policies do not constitute authorization or guarantee of coverage of particular procedure, drug, service or supply. Members and providers should refer to the Member contract to determine if exclusions, limitations, and dollar caps apply to a particular procedure, drug, service or supply.

Policy Limitation: Member's Contract Controls Coverage Determinations.
Statutory Notice to Members: The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illnesses or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. The determination of coverage for a particular procedure, drug, service or supply is not based upon the Policies, but rather is subject to the facts of the individual clinical case, terms and conditions of the member's contract, and requirements of applicable laws and regulations. The contract language contains specific terms and conditions, including pre-existing conditions, limitations, exclusions, benefit maximums, eligibility, and other relevant terms and conditions of coverage. In the event the Member's contract (also known as the benefit contract, coverage document, or evidence of coverage) conflicts with the Policies, the Member's contract shall govern. The Policies do not replace or amend the Member's contract.

Policy Limitation: Legal and Regulatory Mandates and Requirements
The determinations of coverage for a particular procedure, drug, service or supply is subject to applicable legal and regulatory mandates and requirements. If there is a discrepancy between the Policies and legal mandates and regulatory requirements, the requirements of law and regulation shall govern.

Reconstructive Surgery
CA Health and Safety Code 1367.63 requires health care service plans to cover reconstructive surgery. "Reconstructive surgery" means surgery performed to correct or repair abnormal structures of the body caused by congenital defects, developmental abnormalities, trauma, infection, tumors, or disease to do either of the following:

(1) To improve function or

(2) To create a normal appearance, to the extent possible.

Reconstructive surgery does not mean "cosmetic surgery," which is surgery performed to alter or reshape normal structures of the body in order to improve appearance.

Requests for reconstructive surgery may be denied, if the proposed procedure offers only a minimal improvement in the appearance of the enrollee, in accordance with the standard of care as practiced by physicians specializing in reconstructive surgery.

Reconstructive Surgery after Mastectomy
California Health and Safety Code 1367.6 requires treatment for breast cancer to cover prosthetic devices or reconstructive surgery to restore and achieve symmetry for the patient incident to a mastectomy. Coverage for prosthetic devices and reconstructive surgery shall be subject to the co-payment, or deductible and coinsurance conditions, that are applicable to the mastectomy and all other terms and conditions applicable to other benefits. "Mastectomy" means the removal of all or part of the breast for medically necessary reasons, as determined by a licensed physician and surgeon.

Policy Limitations: Medicare and Medicaid
Policies specifically developed to assist Health Net in administering Medicare or Medicaid plan benefits and determining coverage for a particular procedure, drug, service or supply for Medicare or Medicaid members shall not be construed to apply to any other Health Net plans and members. The Policies shall not be interpreted to limit the benefits afforded Medicare and Medicaid members by law and regulation.