



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

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Subject **Total Artificial Heart**

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Hyperlink to Related Coverage Policies

Heart Transplantation
Ventricular Assist Devices (VADs)

INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans as well as benefit plans formerly administered by Great-West Healthcare. Please note, the terms of a participant's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a participant's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a participant's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable group benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. Proprietary information of CIGNA. Copyright ©2010 CIGNA

Coverage Policy

CIGNA covers the CardioWest™ Total Artificial Heart (TAH) (SynCardia Systems, Inc., Tucson, AZ) as medically necessary as a bridge to transplantation in individuals who are transplant-eligible and at risk of imminent death from biventricular failure.

CIGNA covers the AbioCor® Implantable Replacement Heart (ABIOMED™, Inc., Danvers, MA) as medically necessary as destination therapy when performed in accordance with the U.S. Food and Drug Administration's (FDA) Humanitarian Device Exemption (HDE) requirements when ALL of the following criteria are met:

- severe biventricular end stage heart disease
- not a cardiac transplant candidate
- age less than 75 years
- multiple inotropic support required
- not treatable by left ventricular assist device (LVAD) as destination therapy
- not weanable from biventricular support, if on such support
- none of the following contraindications:
 - presence of other irreversible end organ dysfunction that would compromise survival
 - inadequate psychosocial support
 - preoperative noninvasive anatomical assessment indicating inadequate fit (i.e., thoracic volume is unable to accommodate the device)

- presence of coagulation disorders
-

General Background

Heart failure can develop from any condition that overloads, damages, or reduces the efficiency of the heart muscle, impairing the ability of the ventricles to fill with or eject blood. Heart muscle may be damaged by myocardial infarction, coronary artery disease, infection, toxic chemical exposure, or years of untreated hypertension or heart valve abnormality. Treatment of heart failure includes pharmacologic interventions, including diuretics, angiotensin-converting enzyme inhibitors, vasodilators, digitalis, and beta-blockers. Pharmacologic therapy is ineffective in approximately 40% of heart failure patients, however. Heart transplantation is the most effective treatment for advanced heart failure, with most transplant centers achieving one-year survival rates of 85% or greater. Most transplant recipients can expect a ten-year survival of approximately 50%. The demand for donor hearts far exceeds the available supply, however (ECRI, 2008).

As patients become more hemodynamically compromised, there is an increased risk of death prior to transplantation, as well as a less favorable outcome following transplantation. External or implantable ventricular assist devices (VADs) are therefore used for many patients with end-stage heart failure while awaiting transplantation. Timely use of VADs may be successful in preventing further deterioration and reversing metabolic, cellular and nutritional compromise. The temporary use of these mechanical devices is referred to as “bridging” to transplant. VADs are usually inadequate as a bridge to transplant for patients with severe biventricular disease, and two paracorporeal devices may be needed. The total artificial heart may be indicated as a bridge to transplantation for certain patients when VADs and biventricular assist devices are contraindicated. A fully implantable heart may also be considered as a permanent cardiac replacement, or “destination therapy”, for patients with end-stage heart disease who are not candidates for heart transplantation (ECRI, 2008, Copeland et al., 2004).

U.S. Food and Drug Administration (FDA)

CardioWest™ Total Artificial Heart (TAH) (SynCardia Systems, Inc., Tucson, AZ): The CardioWest TAH 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. In the U.S., it is powered by a large console on wheels that requires inpatient hospitalization, although in Europe, portable drivers are used.

AbioCor® Implantable Replacement Heart (IRH) (ABIOMED™, Inc., Danvers, MA): The AbioCor IRH is an artificial heart with completely internal components designed to provide circulatory control in order to prolong life and provide an acceptable quality of life. The internal components of the AbioCor system consist of the thoracic unit, implanted controller, implanted battery, and implanted transcutaneous energy transfer (TET) coil. The external components include the console and patient-carried electronics. The controller monitors and controls 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 up to two hours of freedom of movement. When the patient is sleeping, or when the batteries are being recharged, the system is plugged into an electrical outlet (Samuels and Dowling, 2003; U.S. FDA, 2006).

The AbioCor IRH received FDA Humanitarian Device Exemption (HDE) approval on September 5, 2006, for use in severe biventricular end stage heart disease patients who are not cardiac transplant candidates and who:

- are less than 75 years old
- require multiple inotropic support
- are not treatable by LVAD destination therapy, and
- are not weanable from biventricular support, if on such support

The FDA Summary of Safety and Probable Benefit includes the following contraindications:

- Presence of other irreversible end organ dysfunction that would compromise survival
- Inadequate psychosocial support

- Preoperative noninvasive anatomical assessment indicating inadequate fit (i.e. thoracic volume is unable to accommodate the device)
- Presence of coagulation disorders

In order to receive HDE approval, a manufacturer must first be granted a Humanitarian Use Device (HUD) exemption by demonstrating that the device is designed to treat or diagnose a disease or condition that affects fewer than 4,000 people in the U.S. per year. Although data demonstrating the safety and probable clinical benefit are required for HDE approval, clinical trials evaluating the effectiveness of the device are not required. Following HDE approval, the hospital or healthcare facility institutional review board (IRB) must also approve the use of the device at that institution before it may be used in a patient. The regulatory basis for approving an HDE is that the device must not pose an unreasonable risk of illness or injury and the probable benefit of the device must outweigh the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment. In the AbioCor HDE Summary of Safety and Probable Benefit, the FDA explained its decision to grant an HDE, stating that the preclinical, animal and clinical data all demonstrated that the device is able to achieve the desired level of cardiac support. Although the clinical study results indicated a concern regarding long-term reliability, changes have been made to the device that the FDA believes will improve reliability and durability. In determining whether the benefit of the device outweighs the risk, the FDA also took into account currently available devices and alternate treatments, determining that this is a patient population for whom there is no other treatment option. The FDA summary also states that, in order to address concerns with inadequate anticoagulation, AbioCor has established an anticoagulation committee which proposed a revised anticoagulation protocol to be used in the post-approval study.

The FDA HDE approval includes a requirement for a post-approval study to follow the first 25 patients implanted with the AbioCor IRH until death while on the device, or other outcome (e.g., elective termination by family, device malfunction, etc.). The post-approval study is currently in progress.

Literature Review

CardioWest Total Artificial Heart (TAH): Roussel et al. (2009) evaluated comorbidity and survival of patients who received circulatory support with a CardioWest TAH while awaiting heart transplantation from 1990–2006 (n=42, 40 men, 2 women) at a single center in France. All patients were in cardiogenic shock despite maximum inotropic support at the time of implantation. Idiopathic or dilated cardiomyopathy was diagnosed in 19 patients and ischemic cardiomyopathy in 18 patients. Other diagnoses included postcardiotomy heart failure, fulminant myocarditis, and primary graft failure-rejection. Fourteen patients were receiving intra-aortic balloon pump support, six were receiving mechanical ventilation, and six had undergone cardiopulmonary resuscitation within the previous 24 hours. The duration of support was 1–292 days (mean 101 ± 86 days). Twelve patients died (28.5%) while receiving device support. Causes of death included multi organ failure, sepsis, acute respiratory distress syndrome, and alveolar hemorrhage. Thirty patients underwent transplantation. Actuarial survival rates for transplanted patients at one, five, and ten years were 90% (n=25) 81% (n=14) and 76% (n=10), respectively. Adverse events included stroke in three patients and infections in 35 patients. Significant device malfunctions occurred in four patients, but no malfunctions led to patient death.

Drakos et al. (2006) conducted a retrospective review of 278 patients who had undergone cardiac transplantation between 1993 and 2002. The study assessed the influence of pre-transplant mechanical cardiac support (MCS) on post-transplant outcomes. The authors stated that MCS before heart transplantation was previously associated with worse post-transplant outcomes than when MCS was not required. The study was intended to test the hypothesis that similar outcomes are now seen, regardless of whether MCS is required, due to changes in technology, expertise, patient selection, and timing of transplantation. Of the 278 patients included in the analysis, 72 had required MCS and 206 patients had not. Six of the 72 patients who required MCS received the CardioWest TAH. One month and one year survival did not differ between the groups (MCS 92% and 85%, respectively; no MCS 97% and 92%, respectively). The percentage of patients free from rejection at one year was also similar (MCS: 52%, no MCS: 52%, p=0.60). The incidence of chronic renal insufficiency was lower in the MCS group (15.3% vs. 37.9%, p=.001).

FDA approval of the CardioWest TAH was based on a multicenter controlled clinical trial that demonstrated improved survival rates in selected patients who received the TAH as a bridge to transplant (n=81) compared to a historical control group (n=35) who received a transplant without previous mechanical circulatory support (Copeland, et al., 2004). The primary endpoints of the study included the rates of survival to heart transplantation and of survival after transplantation. All patients were candidates for transplant and were at risk

of imminent death from irreversible biventricular failure. The mean time from entry in the study to transplant was 79.1 days for the TAH group and 8.5 days for the control group. A greater percentage of patients in the TAH group survived to transplant than in the control group (79% vs. 46%, respectively). Overall, one-year survival was 70% in the TAH group and 31% in the control group. The survival rates at one and five years after transplantation in the TAH group were 86% and 64%, respectively, compared to 69% and 34% in the control group. Treatment success was achieved in 69% of the patients in the TAH group, compared to 37% in the control group.

An earlier study of one French center's fifteen-year experience with the Jarvik-7/CardioWest TAH (Leprince, et al., 2003) concluded that the device was a safe and efficient bridge for patients with terminal congestive heart failure awaiting cardiac transplantation. Between 1986 and 2001, 127 patients were bridged to transplantation with the TAH. All were in terminal biventricular failure despite maximum inotropic support. Patients were divided into two groups. Those in Group I had cardiac failure caused by idiopathic or ischemic dilated cardiomyopathy, while those in Group II had cardiac failure caused by diseases of miscellaneous origin. For the most recent period (1998–2001), 74% of patients in Group I received transplants. Survival on the TAH was not as successful for the more difficult patients in Group II, with 50% of patients receiving transplants.

Several published uncontrolled and nonrandomized controlled clinical trials conducted in heart transplantation centers also concluded that the CardioWest TAH was relatively safe and effective as a bridge to transplantation in carefully selected heart transplant candidates (Copeland, et al., 1996, 1998, 1999, 2001; Arabia, et al., 1997).

AbioCor Implantable Replacement Heart (IRH): Dowling et al. (2004) published early results of a multisite feasibility clinical trial evaluating the AbioCor IRH in the treatment of severe, irreversible biventricular heart failure. Patients considered for inclusion in the trial were adults with biventricular failure at maximal medical therapy and dependence on inotropes or inability to tolerate inotropes due to arrhythmia. Patients were excluded if they were candidates for other therapy, including heart transplantation, or had a predicted survival of greater than 30% at 30 days. Additional exclusion criteria included end-organ dysfunction believed to be irreversible, active infection, severe peripheral vascular disease, blood dyscrasia, or recent stroke or transient ischemic attack caused by atherosclerotic disease. Dowling reported on the initial seven adult male patients included in the study. All were in cardiogenic shock despite maximal medical therapy, including intra-aortic balloon pumps. The mean age was 66.7 ± 10.4 years. One intraoperative death occurred due to bleeding, and one early death was caused by a reaction to aprotinin, an intravenously administered protein which helps prevent bleeding following cardiac surgery. There were multiple morbidities related to the severity of illness prior to implantation: five had prolonged intubation; two had hepatic failure (resolved in one); four had renal failure (resolved in three); and one each had recurrent gastrointestinal bleeding, acute cholecystitis requiring laparotomy, respiratory failure that resolved after three days, and malignant hyperthermia that resolved. Three late deaths occurred—one due to multiple system organ failure on postoperative day 56, and one was caused by a cerebrovascular accident (CVA) on postoperative day 142. The latter patient was unable to tolerate anticoagulation. The two patients who had large CVAs were found to have thrombus on the atrial cage struts. These struts were removed for future implants. There was no significant hemolysis or device-related infection. Three patients were able to take multiple trips out of the hospital, and two patients were discharged from the hospital.

Additional results of the AbioCor clinical trial are included in the FDA HDE Summary of Safety and Probable Benefit (2006). The trial was conducted between July 2001 and November 2004. Fourteen patients, including the seven patients included in the previously published early results, were implanted with the device. Twelve of the fourteen patients survived surgery. The mean individual survival time for all 14 patients was 4.5 months, ranging from 0–512 days. The median was 3.6 months. Major adverse events included transient ischemic attack (TIA), surgical bleeding (e.g., tamponade), nonsurgical bleeding, infection unrelated to the device, and respiratory complications. Neurologic, renal, and hepatic complications also occurred. The tendency for bleeding was high; 10 of 12 patients could not tolerate the recommended level of anticoagulation more than 60% of the time, and of these 10, seven could not tolerate it more than 80% of the time. All of the 12 patients who survived the surgery lived the remainder of their lives on the device. Support to six of the 12 was withdrawn secondary to CVAs. There were two device failures. Four patients died of multi-organ failure or sepsis. Of the 12 patients who survived surgery, 10 lived for more than 60 days and were able to interact with family members. Four of these 10 patients had out-of-hospital activities, and the remaining six patients experienced varying degrees of recovery, including walking and in-hospital excursions.

The FDA requires 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. Although not all eligible patients will choose this treatment, the AbioCor IRH provides an option for selected patients with biventricular heart failure who are not candidates for heart transplantation and have no other treatment options.

ECRI Emerging Technology Evidence Report

A 2009 ECRI evidence report evaluated total artificial hearts as a bridge to transplantation and destination therapy. The authors concluded that the evidence is currently insufficient to determine whether a TAH as a bridge to transplantation improves survival and successful recovery compared to optimized medical therapy. Results of the Copeland study suggest improved survival associated with TAH use, but the treatment and control groups had significant baseline differences. This selection bias may confound the comparison between groups. It is unlikely that higher quality trials will ever be conducted, however, because of difficulty in patient recruitment. Bleeding and thromboembolic events were reported in all studies, and infection, renal failure, and device malfunction were also frequently reported. Mortality rates varied significantly across studies. Multi-organ failure was the most frequent cause, which the authors note may have occurred in the absence of TAH treatment.

The authors also concluded that there is insufficient evidence to determine whether a TAH as destination therapy improves patient-oriented outcomes in patients who are not candidates for transplantation. The average patient survival time was in the only available study, a case series of 14 patients, 10 patients survived 60 days, but the percentage of patients who survived without unacceptable deficits is not clear. The average patient survival time was longer than the expected survival time without TAH implantation, although this cannot be definitively determined to be a result of TAH implantation. In terms of adverse events, bleeding, infections, renal dysfunction, thromboembolic events, respiratory failure, and liver failure were frequently reported. The most common cause of death was stroke-related.

Summary

Heart transplantation has become the standard treatment for eligible patients with irreversible biventricular failure unresponsive to medical treatment. The supply of donor hearts has decreased in recent years, however, while the demand has increased significantly. There is adequate evidence to demonstrate that the CardioWest™ Total Artificial Heart (SynCardia Systems, Inc., Tucson, AZ) is a relatively safe and effective bridge to transplantation in carefully selected heart transplant candidates who are at risk of imminent death due to biventricular failure.

The AbioCor® Implantable Replacement Heart (IRH) (Abiomed™ Inc., Danvers, MA) received a U.S. Food and Drug Administration (FDA) Humanitarian Device Exemption (HDE) in 2006. The AbioCor IRH may be a treatment option for carefully selected patients with severe biventricular end-stage heart disease who are not cardiac transplant candidates, are less than 75 years old, require multiple inotropic support, are not treatable by left ventricular assist device (LVAD) destination therapy, and are not weanable from biventricular support, if on such support.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Covered when medically necessary:

CPT®* Codes	Description
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) excluding thoracic unit

ICD-9-CM Diagnosis Codes	Description
428.0	Congestive heart failure, unspecified
428.40	Combined systolic and diastolic heart failure, unspecified
428.41	Combined systolic and diastolic heart failure, acute
428.42	Combined systolic and diastolic heart failure, chronic
428.43	Combined systolic and diastolic heart failure, acute on chronic
428.9	Heart failure, unspecified

*Current Procedural Terminology (CPT®) © 2010 American Medical Association: Chicago, IL.

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	11/15/2007	0281	Total Artificial Heart
Great-West Healthcare	04/07/2006	95.218.06	Transplantation, Heart – Adult
	04/07/2006	95.219.06	Transplantation, Heart – Pediatric

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Connecticut General Life Insurance Company has acquired the business of Great-West Healthcare from Great-West Life & Annuity Insurance Company (GWLA). Certain products continue to be provided by GWLA (Life, Accident and Disability, and Excess Loss). GWLA is not licensed to do business in New York. In New York, these products are sold by GWLA's subsidiary, First Great-West Life & Annuity Insurance Company, White Plains, N.Y.