**Clinical Review Criteria**

**Artificial Hearts**
- AbioCor
- SynCardia

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### Criteria

#### For Medicare Members

<table>
<thead>
<tr>
<th>Source</th>
<th>Policy</th>
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<tbody>
<tr>
<td>CMS Coverage Manuals</td>
<td>None</td>
</tr>
<tr>
<td>National Coverage Determinations (NCD)</td>
<td>Artificial Hearts and Related Devices (20.9)</td>
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<tr>
<td>Local Coverage Determinations (LCD)</td>
<td>None</td>
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<tr>
<td>Local Coverage Article</td>
<td>None</td>
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</tbody>
</table>

#### For Non-Medicare Members

For **Ventricular Assisted Devices**, see specific criteria

**Total artificial hearts with FDA PMA, 510(k), or HDE clearance** may be considered medically necessary as a bridge to heart transplantation in patients meeting **ALL of the following criteria:**
1. Has biventricular heart failure
2. Not responding to medical or surgical treatment
3. Is at imminent risk of death
4. Currently listed as heart transplantation candidate
5. Body size appropriate for the device
6. Is able to tolerate the necessary anticoagulation.

**Total artificial hearts** are considered unproven in all other circumstances, including but not limited to the following:
1. Use as destination therapy
2. Use of a total artificial heart that does not have FDA PMA, 510(k), or HDE clearance

The following information was used in the development of this document and is provided as background only. It is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

### Background

**Artificial Hearts**

Congestive heart failure is a major health problem affecting more than five million patients in the United States. There is a wide variety of options for medical management of heart failure, but many patients eventually deteriorate and fail to respond to any of the medical therapies, and require mechanical circulatory support for survival. In order to provide long-term systemic flow for patients with end-stage heart failure, the National Heart Institute established the artificial heart program in the mid 1960s with the intent to develop a totally implantable mechanical heart.
The AbioCor (Abiomed Inc, Danvers, MA, USA) is the world's first fully implantable total artificial heart. This was first implanted in 2001 at the Jewish Hospital in Louisville, KY. AbioCor is a pneumatically-driven biventricular cardiac support device designed to last at least 18 months. It is made of titanium and Angioflex, a proprietary polyurethane plastic and can produce a flow of up to 8 L/min, sufficient for moderate activity. It is divided into the implantable components and the external drive system. The implanted components consist of the thoracic unit, controller, Transcutaneous Energy Transmission system, and a battery that provides about 30 minutes of power that is designed to allow patients to conduct activities such as taking a shower without an external power source. The external drive system consists of the AbioCor console and support electronics worn or carried by the patient in a waist belt (providing power for 2-4 hours) and an RF communication system for a computer (Samuels 2003, Meyer 2011).

In September 2006, the FDA granted restricted approval of the AbioCor device through the Humanitarian Use Device (HUD) provision. A HUD is a device that the FDA determines is intended to benefit fewer than 4,000 U.S. patients per year. The FDA approval included an agreement by the manufacturer to conduct a post-marketing study, evaluating the AbioCor device in an additional 25 patients. According to the FDA, the AbioCor artificial heart is indicated for use in patients who have both ventricles failing, have end-stage heart disease, are not transplant candidates, are less than 75 years old, are not treatable by single left ventricular heart assist devices for destination therapy, and are not able to be withdrawn from heart support measures. It should not be used for patients who are eligible for a heart transplant, have only left sided heart failure, cannot be successfully treated for blood clotting disorders, or in those where the device will not fit (FDA webpage accessed November 2011).

SynCardia temporary CardioWest™ Total Artificial Heart (TAH), originally developed 30 years ago as the Jarvik TAH and later renamed the CardioWest TAH, continues to be used clinically in over 50 centers within the US and Europe. This is an implantable artificial heart intended to keep hospitalized patients alive while they are waiting for a heart transplant. It is a pulsating bi-ventricular device that is implanted into the chest to replace the patient's left and right ventricles and all four valves of the native heart. The device is sewn to the patient's remaining atria. Hospitalized patients are connected by tubes from the heart through their chest wall to a large power-generating console, which operates and monitors the device. SynCardia was approved by the FDA in 2004 for use only in the hospital as a "bridge to transplant" for patients waiting for a heart transplant who have both sides of their heart failing (biventricular heart failure), do not respond to other treatments, are at imminent risk of death, and are waiting for a donor heart. The temporary CardioWest™ TAH is should not be used in patients who are not eligible for a heart transplant, do not fit the device, cannot be adequately anticoagulated, or have left sided heart failure only (Meyer 2011, FDA Web page accessed November 2011).

SynCardia temporary CardioWest™ Total Artificial Heart (TAH) has not been previously reviewed by MTAC; AbioCor was reviewed by MTAC in 2007 and did not meet its evaluation criteria. The technology is being reviewed due to the coverage of SynCardia temporary CardioWest™ Total Artificial Heart by other health plans as a bridge to heart transplant.

Medical Technology Assessment Committee (MTAC)

AbioCor

04/02/2007: MTAC REVIEW
Evidence Conclusion: There are no published empirical studies on the safety and efficacy of the AbioCor permanent total artificial heart. Unpublished data consists of a feasibility study with 14 patients submitted to the FDA by the device manufacturer. The 12 patients who survived the operation experienced multiple serious adverse effects; only 1 was discharged from the hospital.

Articles: The Medline search yielded 32 articles. These consisted of reviews/commentaries, several empirical studies on technical aspects of the device or device implantation, case reports and 2 case series reporting on 7 patients. The study submitted to the FDA, which included 14 patients, has not been published.

The use of the AbioCor implantable replacement heart in the treatment of irreversible heart failure does not meet the Kaiser Permanente Medical Technology Assessment Criteria.

12/19/2011: MTAC REVIEW
AbioCor
Evidence Conclusion: AbioCor TAH There is no new published evidence after the initial small feasibility study conducted by the AbioCor manufacturer among 14 patients with end-stage heart failure who were not transplant candidates. SynCardia temporary CardioWest™ Total Artificial Heart The published evidence on CardioWest TAH consists of a retrospective study, and a few case series of patients receiving the device as a bridge to transplantation. Due to the eligibility criteria for the implantation, it would be unethical to conduct a randomized
The only valid control would be no intervention as the eligible patients for the implant are those who failed medical therapy, and are not candidates for left ventricular assist device (LVAD). The results of Copeland and colleagues’ case series (Evidence table 1) show that 68% of the critically ill patients who received the CardioWest implant survived to heart transplantation and hospital discharge. Adverse events included bleeding in 20% of cases and device malfunction in 5% of cases. Other complications that occurred at a lower rate included mediastinal infection, fit complications, and stroke. The cause of death was multi-organ failure in 50% of the cases, and sepsis or valve entrapment among the rest. A similar experience was observed in a French study among 42 patients. In this series 12 (28.5%) patients died 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 multi-organ failure (50%), sepsis, acute respiratory distress syndrome, and alveolar hemorrhage. 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.

**Articles:** The literature search for AbioCor total heart transplant did not reveal any study conducted after the initial small feasibility study (Dawling 2003) conducted by the AbioCor manufacturer among 14 patients with end-stage heart failure who were not transplant candidates. The search for SynCardia CardioWest temporary TAH identified a few case series for patients who received the device as a bridge to transplantation, and a retrospective study comparing the device to left ventricular assist devices. The larger case series was selected for critical appraisal. Copeland JG, Smith RG, Arabia FA, et al. Total artificial heart bridge to transplantation: A 9-year experience with 62 patients. *J Heart Lung Transplant* 2004;23:823-831. See Evidence Table.

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The use of the SynCardia implantable replacement heart in the treatment of irreversible heart failure does meet the Kaiser Permanente Medical Technology Assessment Criteria.