Medical Coverage Policy

Total Artificial Hearts as Permanent Replacement Therapy

☐ Device/Equipment  ☐ Drug  ☐ Medical  ☒ Surgery  ☒ Test  ☐ Other

Effective Date: 11/16/2007  Policy Last Updated: 5/15/2012

☐ Prospective review is recommended/required. Please check the member agreement for preauthorization guidelines.

☒ Prospective review is not required.

Description:

In 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, (Abiomed) is intended for people who are not eligible for a heart transplant and who are not likely to live more than a month without intervention. The use of the AbioCor Implantable Replacement Heart would be considered a permanent replacement therapy (i.e., destination therapy - defined as permanent replacement therapy for patients with end-stage heart disease who are not candidates for human heart transplantation due to age or other co-morbidities).

In 2004, a temporary total artificial heart by CardioWest received U.S. Food and Drug Administration (FDA) approval as a bridge to transplantation. This device is unique in that a pulsatile biventricular device is placed after the native ventricles are excised. The labeled indication states that this device should only be used in an inpatient setting. The pulsatile biventricular total artificial heart device with FDA approval, (e.g., the CardioWest device) may be considered medically necessary as a bridge to heart transplantation for patients with biventricular failure who are currently listed as heart transplantation candidates.

As of May 1, 2008, The Centers for Medicare and Medicaid Services (CMS) published a decision memorandum stating that the evidence reviewed to date is inadequate to conclude that the use of an artificial heart is reasonable and necessary, but suggested that the evidence for the use of artificial hearts has the potential to improve health outcomes for Medicare beneficiaries and supports additional research for these devices. Artificial hearts will be covered by Medicare under Coverage with Evidence Development when the member is enrolled in a clinical study that meets all of the criteria required by CMS. ¹
The studies that are approved by CMS must meet the following criteria as noted

The clinical study must address at least one of the following questions:

- Were there unique circumstances such as expertise available in a particular facility or an unusual combination of conditions in particular patients that affected their outcomes?
- What will be the average time to device failure when the device is made available to larger numbers of patients?
- Do results adequately give a reasonable indication of the full range of outcomes (both positive and negative) that might be expected from more wide spread use?

The clinical study must meet all of the following criteria:

- The study must be reviewed and approved by the Food and Drug Administration.
- The principal purpose of the research study is to test whether a particular intervention potentially improves the participants’ health outcomes.
- The research study is well supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.
- The research study does not unjustifiably duplicate existing studies.
- The research study design is appropriate to answer the research question being asked in the study.
- The research study is sponsored by an organization or individual capable of executing the proposed study successfully.
- The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found at 45 CFR Part 46. If a study is FDA-regulated it also must be in compliance with 21 CFR Parts 50 and 56.
- All aspects of the research study are conducted according to appropriate standards of scientific integrity (see [http://www.icmje.org](http://www.icmje.org)).
- The research study has a written protocol that clearly addresses, or incorporates by reference, the standards listed here as Medicare requirements for CSP or CED coverage.
- The clinical research study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Trials of all medical technologies measuring therapeutic outcomes as one of the objectives meet this standard only if the disease or condition being studied is life threatening as defined in 21 CFR § 312.81(a) and the patient has no other viable treatment options.
- The clinical research study is registered on the ClinicalTrials.gov website by the principal sponsor/investigator as demonstrated by having a National Clinical Trial control number.
- The research study protocol specifies the method and timing of public release of all prespecified outcomes to be measured including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 24 months of the end of data collection. If a report is planned to be published in a peer reviewed journal, then that initial release may be an abstract that meets the requirements of the International Committee of Medical Journal Editors.
However, a full report of the outcomes must be made public no later than three (3) years after the end of data collection.

- The research study protocol must explicitly discuss subpopulations affected by the treatment under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria affect enrollment of these populations, and a plan for the retention and reporting of said populations on the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.
- The research study protocol explicitly discusses how the results are or are not expected to be generalizable to the Medicare population to infer whether Medicare patients may benefit from the intervention. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability or Medicaid eligibility.

Other applications of a pulsatile biventricular total artificial heart device (e.g., the CardioWest device) are considered not medically necessary.

In order to receive an 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 percent of women and for many men.

Medical Criteria:

For BlueCHIP for Medicare members only:
Artificial hearts will be covered when the member is enrolled in a CMS approved clinical study that is listed at the following web site: http://www.cms.hhs.gov/MedicareApprovedFacilitie/06_artificialhearts.asp#TopOfPage

For all other product lines:
The AbioCor Implantable Replacement Heart, (Abiomed) is intended for people who are not eligible for a heart transplant and is considered not medically necessary including, but not limited to, its use as permanent replacement therapy (destination therapy).

Total artificial hearts with FDA-approved devices may be considered medically necessary as a bridge to heart transplantation for patients with biventricular failure who are currently listed as heart transplantation candidates.

Policy:

For BlueCHIP for Medicare members:
The implantation of total artificial hearts is considered medically necessary for BlueCHIP for Medicare members only when the member is enrolled in a clinical study that meets specific criteria listed in the above referenced web site.
Medicare policy is developed separately from BCBSRI policy. Medicare policy incorporates consideration of governmental regulations from CMS (Centers for Medicare and Medicaid Services), such as national coverage determinations or local coverage determinations. In addition to benefit differences, CMS may reach different conclusions regarding the scientific evidence than does BCBSRI. Medicare and BCBSRI policies may differ. However, BlueCHiP for Medicare members must be offered, at least, the same services as Medicare offers.

For all other product lines:
The implantation of total artificial hearts as permanent replacement therapy is considered not medically necessary.

There is inadequate scientific evidence to permit conclusions on health outcomes related to the use of total artificial hearts for other conditions or diseases including, but not limited to, their use as permanent replacement therapy (destination therapy).

Total artificial hearts with FDA-approved devices may be considered medically necessary as a bridge to heart transplantation for patients with biventricular failure who are currently listed as heart transplantation candidates.

Coverage:
Benefits may vary between groups/contracts. Please refer to the appropriate evidence of coverage, or subscriber agreement, for applicable surgery services, and not medically necessary benefits/coverage.

Coding:
The following codes are considered not medically necessary:
0051T
0052T
0053T

Related Topics:
The Ventricular Assist Devices and Total Artificial Hearts policy was archived in November of 2007. Ventricular Assist Devices are considered covered services.

Published:
Policy Update, Jan 2008
Provider Update, Apr 2009
Provider Update, Mar 2010
Provider Update, Dec 2011
Provider Update, Jul 2012

References:
Ventricular Assist Devices and Total Artificial Hearts. Policy # 7.03.11. Retrieved on September 11, 2007 and May 6, 2009 from BCBSA Web site:
NCD for Artificial Hearts and Related Devices (20.9). Publication # 100-3. Retrieved on September 11, 2007 and May 6, 2009 from CMS Web site:


1 Centers for Medicare and Medicaid (CMS) Decision Memo for Artificial Hearts (CAG-00322N). Date: 05/01/08. Retrieved on 05/05/08 from:

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