Medical Coverage Policy | Total Artificial Hearts as Permanent Replacement Therapy

EFFECTIVE DATE: 11|06|2007
POLICY LAST UPDATED: 09|01|2015

OVERVIEW

This medical policy documents coverage for Total Artificial Hearts as Permanent Replacement Therapy. The total artificial heart (TAH) replaces the native ventricles and is attached to the pulmonary artery and aorta; the native heart is typically removed. TAH may be used as a bridge to heart transplantation or as destination therapy in those who are not candidates for transplantation.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

BlueCHiP for Medicare

The implantation of total artificial hearts is considered medically necessary for BlueCHiP for Medicare members when the member is enrolled in a CMS-approved clinical study that is listed at the following website: http://www.cms.hhs.gov/MedicareApprovedFacilitie/06_artificialhearts.asp#TopOfPage

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 that Medicare offers.

Commercial Products

Total artificial hearts with U.S. Food and Drug Administration (FDA)-approved devices may be considered medically necessary as a bridge to heart transplantation for patients with biventricular failure who have no other reasonable medical or surgical treatment options, who are ineligible for other univentricular or biventricular support devices, and are currently listed as heart transplantation candidates or are undergoing evaluation to determine candidacy for heart transplantation, and not expected to survive until a donor heart can be obtained.

The implantation of total artificial hearts as permanent replacement therapy is considered not medically necessary as there is insufficient peer-reviewed scientific literature that demonstrates that the procedure/service is effective.

The use of non-FDA-approved or -cleared implantable ventricular assist devices or total artificial hearts is considered non-covered.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for limitations of benefits/coverage when services are not medically necessary.

BACKGROUND

The TAH replaces the native ventricles and is attached to the pulmonary artery and aorta; the native heart is typically removed. TAH may be used as a bridge to heart transplantation or as destination therapy in those who are not candidates for transplantation.

Heart failure may be the consequence of a number of differing etiologies, including ischemic heart disease, cardiomyopathy, congenital heart defects, or rejection of a heart transplant. The reduction of cardiac output is considered to be severe when systemic circulation cannot meet the body's needs under minimal exertion. Heart transplantation improves quality of life and has survival rates at 1, 5, and 10 years of 88%, 74%, and 55%, respectively. The supply of donor organs has leveled off, while candidates for transplants are increasing, compelling the development of mechanical devices.

Initial research into mechanical assistance for the heart focused on the total artificial heart, a biventricular device that completely replaces the function of the diseased heart. An internal battery required frequent recharging from an external power source. Many systems use a percutaneous power line, but a transcutaneous power-transfer coil allows for a system without lines traversing the skin, possibly reducing the risk of infection. Because the heart must be removed, failure of the device is synonymous with cardiac death.

In October 2004, device CardioWest™ Temporary Total Artificial Heart (SynCardia Systems, Inc., Tucson, AZ) was approved by the FDA through the premarket approval process for use as a bridge to transplant in cardiac transplant-eligible candidates at risk of imminent death from biventricular failure. Also, the temporary CardioWest™ Total Artificial Heart (TAH-t) is intended for use inside the hospital. In April 2010, the FDA approved a name-change to Syncardia Temporary Total Artificial Heart.

In September 2006, the AbioCor® Implantable Replacement Heart System (AbioMed, Inc., Danvers MA) was approved by the FDA through the Humanitarian Device Exemption (HDE) process for use in severe biventricular end-stage heart disease individuals who are not cardiac transplant candidates and who:

- Are younger than 75 years of age
- Require multiple inotropic support
- Are not treatable by left ventricular assist devices (LVAD) destination therapy; and
- Are not weanable from biventricular support if on such support.

In addition to meeting other criteria, patients who are candidates for the AbioCor TAH must undergo a screening process to determine if their chest volume is large enough to hold the device. The device is too large for approximately 90% of women and for many men.

There is a smaller amount of evidence on the use of TAH as a bridge to transplantation, or as destination therapy. The type of evidence on bridge to transplant is similar to that for left ventricular assist devices (LVAD) (i.e., case series reporting substantial survival rates in patients without other alternatives). Therefore, this evidence is sufficient to conclude that TAH improves outcomes for these patients similar to LVADs and is a reasonable alternative for patients who require bridge to transplantation but who are ineligible for other types of support devices. Although TAHs show promise for use as destination therapy in patients who have no other treatment options, the available data on their use is extremely limited. There is insufficient evidence on the use of TAH as destination therapy to support conclusions about the efficacy of TAH in this setting. For BlueCHiP for Medicare members, TAH as a destination therapy is covered when the member is enrolled in a CMS-approved clinical study.

CODING

BlueCHiP for Medicare

The following codes may be considered medically necessary when used as total heart replacement when the member is enrolled in a CMS-approved clinical study; for correct claims processing append modifier Q0 - Investigational clinical service provided in a clinical research study that is in an approved clinical research study.

0051T 0052T 0053T

Commercial Products

The following codes are considered not medically necessary when used as total heart replacement:

0051T 0052T 0053T

RELATED POLICIES

None

PUBLISHED

Provider Update, November 2015
Provider Update, May 2014
Provider Update, August 2013
Provider Update, July 2012
Provider Update, December 2011
Provider Update, March 2010
Provider Update, April 2009
Policy Update, January 2008

REFERENCES

1. US Department of Health and Human Services. U.S. Organ Procurement and Transplantation Network (OPTN) and the Scientific Registry of Transplant Recipients (SRTR). 2008 OPTN/SRTR Annual Report 1998-2007. Available online at http://optn.transplant.hrsa.gov/ar2008/.

2. Davies RR, Russo MJ, Hong KN et al. The use of mechanical circulatory support as a bridge to transplantation in pediatric patients: an analysis of the United Network for Organ Sharing database. J Thorac Cardiovasc Surg 2008; 135(2):421-7, 27 e1.

3. NCD for Artificial Hearts and Related Devices (20.9). Publication # 100- https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=246&ncdver=5&NCAId=211&ver=20&NcaName=Artificial+Hearts&bc=ACAAAAAAIAAA&

4. Torregrossa G, Morshuis M, Varghese R, et al. Results with SynCardia total artificial heart beyond 1 year. ASAIO J. Nov-Dec 2014; 60(6):626-634. PMID 25158888

5. 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. Jul 2012; 33(14):1787-1847. PMID 22611136

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