

## Evidence Based Guideline

### Ventricular Assist Devices and Total Artificial Hearts

**File Name:** ventricular\_assist\_devices\_and\_total\_artificial\_hearts  
**Origination:** 3/1994  
**Last CAP Review:** 6/2011  
**Next CAP Review:** 6/2012  
**Last Review:** 6/2011

#### Description of Procedure or Service

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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 which completely replaces the function of the diseased heart. An internal battery required frequent recharging from an external power source. Many systems utilize 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.

**Left ventricular assist devices (LVAD).** Implantable ventricular assist devices are attached to the native heart, which may have enough residual activity to withstand a device failure in the short term. In reversible conditions of heart failure, the native heart may regain some function, and weaning and explanting of the mechanical support system after months of use has been described. Ventricular assist devices can be classified as internal or external, electrically or pneumatically powered, and pulsatile or continuous flow. Initial devices were pulsatile, mimicking the action of a beating heart. More recent devices may utilize a pump which provides continuous flow. Continuous devices may move blood in rotary or axial flow.

Surgically-implanted ventricular assist devices represent a method of providing mechanical circulatory support for patients not expected to survive until a donor heart becomes available for transplant or for whom transplantation is otherwise contraindicated or unavailable. They are most commonly used to support the left ventricle, but right ventricular and biventricular devices may be used. The device is larger than most native hearts, and therefore the size of the patient is an important consideration: the pump may be implanted in the thorax or abdomen or remain external to the body. Inflow to the device is attached to the apex of the failed ventricle, while outflow is attached to the corresponding great artery (aorta for left ventricle, pulmonary artery for right ventricle). A small portion of ventricular wall is removed for insertion of the outflow tube; extensive cardiomyotomy affecting the ventricular wall may preclude VAD use. Devices in which the majority of the system's components are external to the body are for short-term use (6 hours to 14 days) only, due to the increased risk of infection and need for careful, in-hospital monitoring. Some circulatory assist devices are placed percutaneously, i.e., are not implanted. These may be referred to as percutaneous VADs. These devices, as well as the intra-aortic balloon pump, are outside the scope of this policy.

**Percutaneous ventricular assist devices (pVAD).** pVADs have been developed for short-term use in patients who require acute circulatory support. These devices are placed through the femoral artery.

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Two different pVADs have been developed, the TandemHeart™ (Cardiac Assist™, Pittsburgh, PA), and the Impella® device (AbioMed™, Aachen, Germany). In the TandemHeart™ system, a catheter is introduced through the femoral artery and passed into the left atrium via transseptal puncture. Oxygenated blood is then pumped from the left atrium into the arterial system via the femoral artery. The Impella device is also introduced through a femoral artery catheter. In this device, a small pump is contained within the catheter that is placed into the left ventricle. Blood is pumped from the left ventricle, through the device, and into the ascending aorta. Adverse events associated with pVAD include access site complications such as bleeding, aneurysms, or leg ischemia. Cardiovascular complications can also occur, such as perforation, myocardial infarction (MI), stroke, and arrhythmias.

There are several situations in which pVAD may offer possible benefits: 1) cardiogenic shock that is refractory to medications and intra-aortic balloon pump (IABP), 2) cardiogenic shock, as an alternative to IABP, and 3) high-risk patients undergoing invasive cardiac procedures who need circulatory support.

### Regulatory Approval

#### **Total Artificial Heart**

In October 2004, device CardioWest™ Temporary Total Artificial Heart was approved by the U.S. Food and Drug Administration (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, device AbioCor® Implantable Replacement Heart System 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. The FDA is requiring the company to provide a comprehensive patient information package to patients and families. To further refine and improve the use of this artificial heart technology, AbioMed will conduct a postmarketing study of 25 additional patients. The postmarket study was recommended by the Circulatory Systems Devices Panel, a part of the FDA's Medical Devices Advisory Committee.

#### **Ventricular Assist Devices**

In December 1995, device Thoratec® Ventricular Assist Device System was approved by the FDA through the premarket approval process for use as a bridge to transplantation in patients suffering from end-stage heart failure. The patient should meet all of the following criteria:

- candidate for cardiac transplantation,
- imminent risk of dying before donor heart procurement, and
- dependence on, or incomplete response to, continuous vasopressor support.

In May 1998, supplemental approval for the above device was given for the indication for postcardiotomy patients who are unable to be weaned from cardiopulmonary bypass. In June 2001, supplemental approval was given for a portable external driver to permit excursions within a 2-hour travel radius of the hospital in the company of a trained caregiver. In November 2003, supplemental approval was given to market the device as Thoratec® Paracorporeal VAD. In August 2004, supplemental approval was given

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to a modified device to be marketed as the Thoratec® Implantable VAD for the same indications. In January 2008, supplemental approval was given to delete Paracorporeal VAD use.

In February 2004, the FDA approved the DeBakey VAD® Child under the HDE approval process. According to the FDA, this device is indicated under HDE for both home and hospital use for children who are between ages 5 and 16 years and who have end-stage ventricular failure requiring temporary mechanical blood circulation until a heart transplant is performed.

In April 2008, continuous flow device HeartMate II® LVAS was approved by the FDA through the premarket approval process for use as a bridge to transplantation in cardiac transplant candidates at risk of imminent death from nonreversible left ventricular failure. The Heartmate II LVAS is intended for use both inside and outside the hospital. In January 2010, the device received the added indication as destination therapy for use in patients with New York Heart Association (NYHA) Class IIIB or IV end-stage left ventricular failure who have received optimal medical therapy for at least 45 of the last 60 days and are not candidates for cardiac transplantation.

In October 2008, device Centrimag® Right Ventricular Assist Device was approved by the FDA under the HDE to provide temporary circulatory support for up to 14 days for patients in cardiogenic shock due to acute right-sided heart failure.

### **Percutaneous Ventricular Assist Devices** (circulatory assist devices)

The Impella® Recover LP 2.5 Percutaneous Cardiac Support System received FDA 510(k) approval in May 2008 for short-term (less than six hours) use in patients requiring circulatory support. The TandemHeart® (Cardiac Assist, Pittsburgh) received a similar 510(k) approval for short-term circulatory support in September 2005.

**\*\*\*Note: This Evidence Based Guideline is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

## **Evidence Based Guideline for Ventricular Assist Devices and Total Artificial Hearts**

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Ventricular assist devices are only covered for FDA-labeled indications.

Ventricular assist devices are recommended when **all** of the following criteria for a given indication are met:

### **A. Bridge to Recovery/ Post-cardiotomy Setting:**

Implantable ventricular assist devices with FDA approval or clearance cleared devices are recommended in the post-cardiotomy setting in patients who are unable to be weaned off cardiopulmonary bypass.

### **B. Bridge to Transplant**

Implantable ventricular assist devices with FDA approval or clearance cleared devices are recommended as a bridge to heart transplantation for patients or who are currently listed as heart transplantation candidates and not expected to survive until a donor heart can be obtained, or are undergoing evaluation to determine candidacy for heart transplantation.

Ventricular assist devices with FDA approval or clearance, including humanitarian device exemptions, are recommended as a bridge to heart transplantation in children aged 5 to 16 who are currently listed as heart transplantation candidates and not expected to survive until a donor heart can be obtained, or are undergoing evaluation to determine candidacy for heart transplantation.

Total artificial hearts with FDA-approved devices are recommended as a bridge to heart transplantation

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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, and not expected to survive until a donor heart can be obtained.

### C. Destination Therapy

1. The patient has **either**:
  - a. New York Heart Association (NYHA) class IV heart failure for  $\geq$  to 60 days, OR
  - b. New York Heart Association (NYHA) class III/IV for 28 days and one of the following:
    - i. received  $\geq$ 14 days support with intraaortic balloon pump or
    - ii. is dependent on IV inotropic agents, with 2 failed weaning attempts

### AND

2. The patient must not be a candidate for human heart transplant for one or more of the following reasons:
  - a. Age is  $>$  65 years; OR
  - b. Insulin dependent diabetes mellitus with end-organ damage; OR
  - c. Chronic renal failure (serum creatinine of  $>$  2.5 mg/dL) for  $\geq$ 90 days); OR
  - d. Presence of other clinically significant condition

Total artificial hearts with FDA-approved devices are recommended 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, and not expected to survive until a donor heart can be obtained.

### Medical Evidence regarding Ventricular Assist Devices and Total Artificial Hearts indicates it is not recommended in the following situations

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Ventricular assist devices are not recommended for any off-label indication.

Ventricular Assist Devices are not recommended when all of the criteria above for a given indication are not met.

Use of a non-FDA approved or cleared ventricular assist device is not recommended.

Other applications of left ventricular devices or total artificial hearts are not recommended, including, but not limited to, the use of total artificial hearts as destination therapy.

### Benefits Application

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This evidence based guideline relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this guideline.

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## **Billing/Coding/Physician Documentation Information**

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This guideline may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at [www.bcbsnc.com](http://www.bcbsnc.com). They are listed in the Category Search on the Medical Policy search page.

*Applicable codes: 33975, 33976, 33977, 33978, 33979, 33980, 33981, 33982, 33983, 93750, 0048T, 0050T, 0051T, 0052T, 0053T Q0478, Q0479, Q0480, Q0481, Q0482, Q0483, Q0484, Q0485, Q0486, Q0487, Q0488, Q0489, Q0490, Q0491, Q0492, Q0493, Q0494, Q0495, Q0496, Q0497, Q0498, Q0499, Q0500, Q0501, Q0502, Q0503, Q0504, Q0505.*

## **Scientific Background and Reference Sources**

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Independent Review by Senior Director, Medical Affairs

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FDA Approval of Thoratec's Bi ventricular assist device

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ECRI Target Fact Sheet, Ventricular assist devices (VADs) for heart failure (short-term bridge to recovery) Target Report #777, March 2000.

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BCBSA Medical Policy Reference Manual, 7.03.11, 7/12/02

Specialty Matched Consultant Advisory Group - 9/2002

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Specialty Matched Consultant Advisory Panel 6/2010

# Ventricular Assist Devices and Total Artificial Hearts

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.11, 9/16/10

Specialty Matched Consultant Advisory Panel review 6/2011

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.11, 9/1/11

## Policy Implementation/Update Information

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12/95 Evaluated: Heartmate IP with indications added to policy based on FDA approval letter.

4/96 Revised: Thoratec's bi ventricular assist device added based on FDA approval on 12/20/95.

4/97 Reaffirmed.

5/99 Criteria adjusted to add hemodynamic criteria for post surgery candidates.

7/99 Reformatted, Medical Term Definitions added

12/99 Reaffirmed, Medical Policy Advisory Group

5/00 Revised. Added the Enhanced External Counterpulsation (EECP) procedure as an external, investigational treatment modality.

9/00 Specialty Matched Consultant Advisory Panel. System coding changes.

10/00 Medical Policy Advisory Group - Revised. Under "When Ventricular Assist Devices are not covered", #2. d., changed statement from "Patients with uncorrected valvular disease" to "Patients with clinically significant uncorrected valvular disease".

3/02 Added codes 33979 and 33980 to the Billing and Coding Section and System Application Guidelines. Format changes.

9/02 Removed Enhanced External Counterpulsation (EECP) from this policy. (See Enhanced External Counterpulsation (EECP) Policy MED1134) Revised Description section for clarity. Sources added. No change in criteria.

3/03 Added criteria for ventricular assist device as a destination therapy for patients with end-stage heart failure.

7/15/04 Additional information added to clarify that the total artificial heart is considered investigational. Codes 0048T, 0049T, 0050T, 0051T, 0052T, and 0053T added to the policy. Specialty Matched Consultant Advisory Panel review with no changes made to policy criteria. Title changed from Ventricular Assist Devices to Ventricular Assist Devices and Total Artificial Hearts. References added. Notification 7/15/2004. Effective date 09/23/2004.

11/03/05 HCPCS code Q0480, Q0481, Q0482, Q0483, Q0484, Q0485, Q0486, Q0487, Q0488, Q0489, Q0490, Q0491, Q0492, Q0493, Q0494, Q0495, Q0496, Q0497, Q0498, Q0499, Q0500, Q0501, Q0502, Q0503, Q0504, Q0505 (effective October 1, 2005) added to the Billing /Coding section of the policy.

3/30/06 Specialty Matched Consultant Advisory Panel review 2/27/06. No changes to policy criteria. Rationale added to Policy Guidelines. Policy number added to Key Words. References updated.

4/21/08 Policy statement revised to indicate that BCBSNC may provide coverage for Total Artificial Hearts as a bridge to heart transplantation when it is determined to be medically necessary because the medical criteria and guidelines outlined in the policy are met. The following statement was added to the When Ventricular Assist Devices and Total Artificial Hearts Are Covered section: "Total artificial hearts with FDA-approved

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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." Deleted the statement "total artificial hearts are beyond the scope of this policy" from the Description section. Deleted the statement "total artificial hearts are considered investigational" from the Not Covered section and added the statement, "Other applications of left ventricular devices or total artificial hearts are considered investigational, including, but not limited to, the use of total artificial hearts as destination therapy." Deleted Item B.5. regarding median duration time on the device. Added CPT Codes 0051T, 0052T, 0053T to Billing/Coding section. References updated. Specialty Matched Consultant Advisory Panel review 3/12/08. Medical Policy changed to Evidence Based Guideline. (adn)

3/2/09 CPT code 0049T deleted.

1/5/10 CPT codes 33981, 33982, 33983 and 93750 added to Billing/Coding section.

8/03/10 Guideline policy number removed. Extensively updated Description section. Added the following statement to Bridge to Transplant section: "Contraindications for bridge to transplant LVADs include conditions that would generally exclude patients for heart transplant. Such conditions are chronic irreversible hepatic, renal, or respiratory failure; systemic infection; and blood dyscrasia. Due to potential problems with adequate function of the VAD, implantation is also contraindicated in patients with uncorrected aortic insufficiency." References updated. Specialty Matched Consultant Advisory Panel review 6/2010. (mco)

1/4/11 Codes Q0478 and Q0479 added to the Billing/Coding section (mco)

7/19/11 Specialty Matched Consultant Advisory Panel review 6/2011. Revised Guidelines. "For Ventricular Dysfunction Following Cardiac Surgery" changed to "Bridge to Recovery: Post Cardiectomy Setting". All specific criteria for this section removed and replaced with the following statement: "Implantable ventricular assist devices with FDA approval or clearance are recommended in the post-cardiectomy setting in patients who are unable to be weaned off cardiopulmonary bypass." "Bridge to Transplant" section revised to state: "Implantable ventricular assist devices with FDA approval or clearance cleared devices are recommended as a bridge to heart transplantation for patients or who are currently listed as heart transplantation candidates and not expected to survive until a donor heart can be obtained, or are undergoing evaluation to determine candidacy for heart transplantation. Ventricular assist devices with FDA approval or clearance, including humanitarian device exemptions, are recommended as a bridge to heart transplantation in children aged 5 to 16 who are currently listed as heart transplantation candidates and not expected to survive until a donor heart can be obtained, or are undergoing evaluation to determine candidacy for heart transplantation. Total artificial hearts with FDA-approved devices are recommended 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, and not expected to survive until a donor heart can be obtained." "Has a peak O2 consumption of < 14 ml/kg" removed from Destination Therapy criteria. References updated. Replaced the terms "medically necessary" and "investigational" with "recommended" and "not recommended." (mco)

11/8/11 Description section extensively revised to include information regarding Percutaneous Ventricular Assist Devices. Device regulatory information updated. References updated. No changes to guideline statements. (mco)

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