Protocol

Total Artificial Hearts and Implantable Ventricular Assist Devices

(70311)

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Preauthorization	Yes	**Review Dates**: 01/10, 01/11, 01/12, 01/13, 05/13, 05/14	

The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. ***Preauthorization is required.*** *Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

Description

A ventricular assist device (VAD) is a mechanical support attached to the native heart and vessels to augment cardiac output. The total artificial heart (TAH) replaces the native ventricles and is attached to the pulmonary artery and aorta; the native heart is typically removed. Both the VAD and TAH may be used as a bridge to heart transplantation or as destination therapy in those who are not candidates for transplantation. The VAD has also been used as a bridge to recovery in patients with reversible conditions affecting cardiac output.

Background

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 one, five, and 10 years of 88%, 74%, and 55%, respectively. (1) 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 cardiotomy affecting the ventricular wall may preclude VAD use.

Percutaneous ventricular assist devices (pVAD). Devices in which the majority of the system's components are external to the body are for short-term use (six 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 (pVADs). The pVADs are placed through the femoral artery. 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.

Intra-aortic balloon pumps are outside the scope of this Protocol.

Regulatory Approval

Total Artificial Heart

In October 2004, device CardioWest™ Temporary Total Artificial Heart (SynCardia Systems, Inc., Tucson, AZ) 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 (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. 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 postmarketing 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 (Thoratec Corp., Pleasanton, CA) was

approved by the U.S. Food and Drug Administration (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:

1. candidate for cardiac transplantation,
2. imminent risk of dying before donor heart procurement, and
3. 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 two-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 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 five 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 (Thoratec, Pleasanton, CA) 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 (Levitronix, Zurich) 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.

In December 2011, the Berlin Heart EXCOR Pediatric VAD was approved via HDE. The indications for this device are pediatric patients with severe isolated left ventricular or biventricular dysfunction who are candidates for cardiac transplant and require circulatory support.

Percutaneous Ventricular Assist Devices (circulatory assist devices)

The Impella® Recover LP 2.5 Percutaneous Cardiac Support System (Abiomed, Aachen, Germany) 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.

VAD Device	Manufacturer	Date of Initial Approval	Method of FDA Clearance	Indication
Thoratec® IVAD	Thoratec	August 2004	PMA Supplement	Bridge to Transplant and post-cardiotomy
DeBakey VAD® Child	MicroMed	April 2004	HDE	Bridge to Transplant in children 5–16 years of age
HeartMate II®	Thoratec	April 2008	PMA	Bridge to Transplant and Destination
Centrimag®	Levitronix	October 2008	HDE	Postcardiotomy

pVAD Device	Manufacturer	Date of initial Approval	Method of FDA clearance	Indication
Impella®	Abiomed	May 2008	510(k)	Partial circulatory support using an extracorporeal bypass control unit. for periods up to 6 hours
TandemHeart®	Cardiac Assist	September 2005	510(k)	Temporary left ventricular bypass of 6 hours or less

Several other devices are in clinical trials or awaiting FDA review.

Related Protocols

Heart/Lung Transplant

Heart Transplant

Policy (Formerly Corporate Medical Guideline)

Post-cardiotomy Setting/Bridge to Recovery

Implantable ventricular assist devices with FDA approval or clearance may be considered **medically necessary** in the post-cardiotomy setting in patients who are unable to be weaned off cardiopulmonary bypass.

Bridge to Transplantation

Implantable ventricular assist devices with FDA approval or clearance may be considered **medically necessary** as a bridge to heart transplantation for patients 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, may be considered **medically necessary** as a bridge to heart transplantation in children 16 years old or younger 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 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.

Destination Therapy

Implantable ventricular assist devices with FDA approval or clearance may be considered **medically necessary** as destination therapy with end-stage heart failure patients who are ineligible for human heart transplant and who meet the following "REMATCH Study" criteria:

- New York Heart Association (NYHA) class IV heart failure for ≥ 60 days, OR patients in NYHA class III/IV for 28 days, received ≥ 14 days' support with intra-aortic balloon pump or dependent on IV (intravenous) inotropic agents, with two failed weaning attempts.

In addition, patients must not be candidates for human heart transplant for one or more of the following reasons:

- Age > 65 years; OR
- Insulin-dependent diabetes mellitus with end-organ damage; OR
- Chronic renal failure (serum creatinine > 2.5 mg/dL for ≥ 90 days); OR

- Presence of other clinically significant condition.

Other Indications

Other applications of implantable ventricular devices or total artificial hearts are considered **investigational**, including, but not limited to, the use of total artificial hearts as destination therapy. The use of non-FDA approved or cleared implantable ventricular assist devices or total artificial hearts is considered **investigational**.

Percutaneous ventricular assist devices (pVAD) are considered **investigational** for all indications.

Policy Guideline

Only two ventricular assist devices (VADs) have approval from the U.S. Food and Drug Administration (FDA) for the pediatric population. The DeBakey VAD® Child device and the Berlin Heart EXCOR Pediatric VAD have FDA approval through the humanitarian device exemption (HDE) process. The DeBakey VAD is indicated for use in children ages five to 16 years who are awaiting a heart transplant, i.e., as a bridge to transplant while the Berlin Heart EXCOR VAD is indicated for children with severe isolated left ventricular or biventricular dysfunction who are candidates for cardiac transplant and require circulatory support

In general, candidates for bridge-to-transplant implantable ventricular assist devices (VADs) are those who are considered appropriate heart transplant candidates but who are unlikely to survive the waiting period until a human heart donor is available. Some studies have included the following hemodynamic selection criteria: either a left atrial pressure of 20 mm Hg or a cardiac index of < 2.0L/min/m while receiving maximal medical support. Patients with VADs are classified by the United Network for Organ Sharing (UNOS) as Status I, that is, persons who are most ill and are considered the highest priority for transplant.

The median duration for time on the device is between 20 and 120 days.

Contraindications for bridge to transplant VADs and TAH include conditions that would generally exclude patients for heart transplant. Such conditions are chronic irreversible hepatic, renal, or respiratory failure; systemic infection; coagulation disorders and inadequate psychosocial support. Due to potential problems with adequate function of the VAD or TAH, implantation is also contraindicated in patients with uncorrected valvular disease. See also Protocol on Heart Transplant for further discussion of heart transplant candidacy.

In addition, individuals must have sufficient space in the thorax and/or abdominal cavity for the device. In the case of the CardioWest™ temporary Total Artificial Heart, this excludes individuals with body surface areas less than 1.7 m^2 or who have a distance between the sternum and 10^{th} anterior rib of less than 10 cm as measured by CT [computed tomography] scan.

Medicare Advantage

Ventricular assist devices are **medically necessary** postcardiotomy (following open-heart surgery). They must have received approval from the Food and Drug Administration (FDA) for that purpose, and they are used according to the FDA-approved labeling instructions.

VADs are **medically necessary** as bridge-to-transplant. They must have received approval from the FDA for that purpose, and be used according to the FDA-approved labeling instructions. All of the following criteria must also be met in order for a VAD to be **medically necessary** as a bridge-to-transplant:

a. The patient is approved and listed as a candidate for heart transplantation by a Medicare-approved heart transplant center; and,

b. The implanting site, if different than the Medicare-approved transplant center, must receive written permission from the Medicare-approved heart transplant center under which the patient is listed prior to implantation of the VAD.

The Medicare-approved heart transplant center should make every reasonable effort to transplant patients on such devices as soon as medically reasonable. Ideally, the Medicare-approved heart transplant centers should determine patient-specific timetables for transplantation, and should not maintain such patients on VADs if suitable hearts become available.

An artificial heart for bridge-to-transplantation may have potential to be covered as a clinical trial. Clinical trials are paid by original Medicare and not Medicare Advantage plans.

The VADs used for destination therapy are **medically necessary** only if they have received approval from the FDA for that purpose, and the device is used according to the FDA-approved labeling instructions.

The VADs are **medically necessary** for patients who have chronic end-stage heart failure (New York Heart Association Class IV end-stage left ventricular failure) who are not candidates for heart transplantation, and meet all of the following conditions:

a. Have failed to respond to optimal medical management (including beta-blockers and ACE inhibitors if tolerated) for at least 45 of the last 60 days, or have been balloon pump-dependent for seven days, or IV (intravenous) inotrope-dependent for 14 days; and,

b. Have a left ventricular ejection fraction (LVEF) < 25%, and,

c. Have demonstrated functional limitation with a peak oxygen consumption of < 14 ml/kg/min unless balloon pump- or inotrope-dependent or physically unable to perform the test.

Facility Criteria

Facilities which are approved to provide VAD for as destination therapy are listed at this web site: http://www.cms.gov/MedicareApprovedFacilitie/VAD/list.asp#TopOfPage.

Prospective VAD recipients must receive all information necessary to assist them in giving appropriate informed consent for the procedure so that they and their families are fully aware of the aftercare requirements and potential limitations, as well as benefits, following VAD implantation.

Artificial hearts as destination therapy may have potential to be covered as a clinical trial. Clinical trials are paid by original Medicare and not Medicare Advantage plans.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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