Implantable Ventricular Assist Devices

Description

Mechanical devices to assist or replace a failing heart have been developed over many decades of research. A ventricular assist device (VAD) is a mechanical support attached to the native heart and vessels to augment cardiac output. The VAD 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 1, 5, and 10 years of 89%, 75%, and 56%, respectively. (1) The supply of donor organs has leveled off, while candidates for transplants are increasing, compelling the development of mechanical devices.

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. Devices
that are more recent 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. 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.

**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. 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, 3) high-risk patients undergoing invasive cardiac procedures who need circulatory support, and 4) patients completing cardiotomy surgery to allow the heart muscle to heal.

**Regulatory Status**

**Ventricular Assist Devices**

In December 1995, Thoratec® Ventricular Assist Device System (Thoratec Corp., Pleasanton, CA) 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:

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.

April 25, 2012 the FDA Advisory Committee voted to recommend device approval as a bridge to transplant for end stage heart failure for the HeartWare (HeartWare Int., Inc.) intrapericardial, continuous-flow, centrifugal pump device. This device remains investigational until FDA approval has been granted.

Since the initial device was approved, many others have been approved for marketing or by the human device exemption (See Table below).

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

The TandemHeart® (Cardiac Assist, Pittsburgh) received FDA 510(k) approval in May 2005 for short-term (less than 6 hours) use in patients requiring circulatory support. The Impella® Recover LP 2.5 Percutaneous Cardiac Support System (Abiomed, Aachen, Germany) received a similar 510(k) approval for short-term circulatory support in September 2008.
Since the initial device was approved, many others have been approved for marketing or by the human device exemption (See Table below).

<table>
<thead>
<tr>
<th>VAD Device</th>
<th>Manufacturer</th>
<th>Date of Initial Approval</th>
<th>Method of FDA clearance</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>HeartMate XVE</td>
<td>Thoratec</td>
<td>2003</td>
<td>HDE</td>
<td>Pulsatile</td>
</tr>
<tr>
<td>Thoratec® IVAD</td>
<td>Thoratec</td>
<td>August 2004</td>
<td>PMA Supplement</td>
<td>Bridge to Transplant and post-cardiotomy. Authorized only for internal implant, not for paracorporeal implant due to reliability issues.</td>
</tr>
<tr>
<td>DeBakey VAD®</td>
<td>MicroMed</td>
<td>April 2004</td>
<td>HDE</td>
<td>Bridge to Transplant in children 5–16 years of age</td>
</tr>
<tr>
<td>HeartMate II®</td>
<td>Thoratec</td>
<td>April 2008</td>
<td>PMA</td>
<td>Bridge to Transplant and Destination</td>
</tr>
<tr>
<td>Centrimag®</td>
<td>Levitronix</td>
<td>October 2008</td>
<td>HDE</td>
<td>Post cardiotomy</td>
</tr>
<tr>
<td>HVAD®</td>
<td>HeartWare</td>
<td>October 2008</td>
<td>PMA</td>
<td>Initiated US BTT trial in October 2008 (completed February 2010) and US DT trial in August 2010. Miniature &quot;third generation&quot; device with centrifugal blood path and hydromagnetically suspended rotor that may be placed in the pericardial space.</td>
</tr>
<tr>
<td>Stratos LV CRT-P and Stratos LV-T CRT-P</td>
<td>Biotronik, Inc.</td>
<td>May 2008</td>
<td>PMA</td>
<td>For patients who have moderate to severe heart failure (NYHA class II I/IV), including left ventricular dysfunction (EF&lt;35%) and QRS &gt;120 ms and remain symptomatic.</td>
</tr>
</tbody>
</table>
Contak | Guidant Corp | May 2008 | PMA | For patients with moderate to severe heart failure who remain symptomatic despite stable, optimal heart failure drug therapy and have left ventricular dysfunction.

HeartMate III® | Thoratec | 2010 | PMA Supplement | Continuous flow driven by a magnetically suspended axial flow rotor.

EXCOR® | Berlin Heart | July 21, 2011 | HDE | Pediatric VAD

<table>
<thead>
<tr>
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<th>Date of initial Approval</th>
<th>Method of FDA clearance</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>TandemHeart®</td>
<td>Cardiac Assist</td>
<td>September 2005</td>
<td>510(k)</td>
<td>Temporary left ventricular bypass of 6 hours or less.</td>
</tr>
<tr>
<td>Impella® LP 2.5, 5.0, &amp;LD</td>
<td>Abiomed</td>
<td>May 2008</td>
<td>510(k)</td>
<td>Partial circulatory support using an extracorporeal bypass control unit. for periods up to 6 hours.</td>
</tr>
</tbody>
</table>

Source: U. S. Food and Drug Administration, Medical Devices. Several other devices are in clinical trials or awaiting FDA/Congressional review.

**Related Policies**

7.03.08 Heart/Lung Transplant
7.03.09 Heart Transplant
Policy

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

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 aged 5 to 16 years 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.

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 inotropic agents, with 2 failed weaning attempts.

In addition, patients must not be candidates for human heart transplant for 1 or more of the following reasons:

- 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 are considered **not medically necessary**. The use of non-FDA approved or cleared implantable ventricular assist devices is considered **investigational**.

Percutaneous ventricular assist devices (pVADs) are considered **not medically necessary** for all indications.

Policy Guidelines

Only one ventricular assist device (VAD) has approval from the U.S. Food and Drug Administration (FDA) for the pediatric population. The DeBakey VAD® Child device has FDA approval (HDE process) for use in children ages 5 to 16 years who are awaiting a heart transplant, i.e., as a bridge to transplant.

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 <2.0 L/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 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, implantation is also contraindicated in patients with uncorrected valvular disease.
Rationale

Literature Review

The literature review focuses on 3 situations: short-term use of the ventricular assist device (VAD) for cardiac shock following cardiac surgery, use of the VAD as a bridge to heart transplant, and use of the VAD as destination therapy in end-stage heart failure.

Bridge to Recovery: Post-cardiotomy Setting

Five studies of the Centrimag Right Ventricular Assist Device (RVAS) included between 12 and 32 patients, the majority of whom received biventricular devices. (2-4) Indications (and numbers of patients) in these 5 studies were: support for post-cardiotomy cardiogenic shock (bridge to recovery, n=53), bridge to long-term device implantation (n=9), treatment of right heart failure in patients who previously received left ventricular assist devices (LVADs) (n=15), bridge to later decision when neurologic status is clarified (n=16), and acute donor graft failure (n=6). The mean time on mechanical circulatory support ranged from 9.4 days to 46.9 days. The 30-day mortality rates were between 17% and 63%. The proportion of patients discharged from the hospital was between 30% and 83%. Major complications included bleeding requiring reoperation, sepsis, and stroke. No device failures were observed in these studies.

Bridge to Transplant: Left Ventricular Assist Devices

A 1996 Blue Cross and Blue Shield Association Technology Evaluation Center (TEC) assessment concluded that left ventricular assist devices (LVADs) could provide an effective bridge to transplantation. (5) Goldstein and colleagues published a more recent review. (6) It should be recognized that LVADs do not change the number of patients undergoing heart transplantation due to the fixed number of donor hearts. However, the VAD will categorize its recipient as a high-priority heart transplant candidate. Published studies continue to report that the use of a VAD does not compromise the success of a subsequent heart transplant and, in fact, may improve post-transplant survival, thus improving the use of donor hearts. (7-10) Currently available implantable LVADs consist of pulsatile devices that require stiff power vent lines that perforate the skin and implantable
pump chambers, as well as non-pulsatile axial flow systems of smaller size and lower noise levels. (11)

In 6 reports, with samples ranging from 32 to 279 patients, most participants received the continuous-flow device as a bridge to transplantation. (12-17) Survival rates at 6 months were between 67% and 87%, and between 50% and 80% at 1 year. These rates are similar to those observed in a recent report of a federal circulatory support device registry. (18) A study by Patel and colleagues compared HeartMate I and HeartMate II recipients at a single center, finding the same 1-year survival and similar rates of subsequent development of right heart failure. (14) Serious adverse events occurring after HeartMate II-implantation include bleeding episodes requiring reoperation, stroke, infection, and device failure.

In December 2009, Slaughter and colleagues published data from an unblinded randomized multicenter trial. (19) Subjects were randomly assigned to continuous-flow or pulsatile-flow devices on a 2:1 block-randomization basis. The primary outcome measured was a composite endpoint of 2-year survival, free of disabling stroke or need for device replacement. Continuous-flow patients (n=134) reached the primary outcome at a rate of 46% (95% confidence interval [CI]: 38-55) compared to pulsatile-flow patients’ (n=66) rate of 11% (95% CI: 3-18), which was a significant difference (p<0.001). Analysis of constituent factors indicated that a lower rate of devices needing replacement in the continuous-flow group had the largest effect on the composite endpoint; 2-year death rate also favored this device (58% vs. 24%, respectively; p=0.008). Stroke and death (within 2 years of implantation) were similar in the 2 groups (stroke rate 12% and death rate 36%). Quality-of-life scores were also similar in the 2 groups. Although unblinded, this randomized trial adds to the evidence favoring continuous-flow devices.

There is one FDA-approved device, via the Humanitarian Device Exemption (HDE) process, available for use as a bridge to cardiac transplant in children. This HDE approval was based on data from children who were a part of the initial clinical studies of this device. (20) Publications have reported positive outcomes for children using VADs as a bridge to transplantation. Using the United Network for Organ Sharing (UNOS) database, Davies et al. reported on use of VADs in pediatric patients undergoing heart transplantation. (21) Their
analysis concluded that pediatric patients requiring a pretransplantation VAD have similar long-term survival to those not receiving mechanical circulatory support.

In 2011, Strueber et al. (22) published a case series of 50 patients awaiting heart transplantation treated with a newer generation HeartWare® VAD. This device was smaller than previous versions and implanted within the pericardial space. Patients were followed until transplantation, myocardial recovery, device explant, or death. The median duration of time on the LVAD was 322 days. Nine patients died, 3 from sepsis, 3 from multiple organ failure, and 3 from hemorrhagic stroke. At the end of follow-up, 20 patients had undergone transplant (40%), 4 had the pump explanted (8%), and the remaining 17 continued on pump support (34%). The most common complications were infection and bleeding. Twenty-one patients had infections (42%), and 5 patients had sepsis (10%). Bleeding complications occurred in 15 patients (30%), 10 of whom (20%) required surgery for bleeding.

The Evaluation of the HeartWare Left Ventricular Assist Device for the Treatment of Advanced Heart Failure (ADVANCE) trial studied 140 patients from 30 US hospitals who received the HeartWare investigational device and 499 patients received a commercially available pump implanted contemporaneously. (23) Success occurred in 90.7% of investigational pump patients and 90.1% of controls, establishing the noninferiority of the investigational pump ($P<0.001; 15\%$ noninferiority margin). At 6 months, median 6-minute walk distance improved by 128.5 m, and both disease-specific and global quality-of-life scores improved significantly. The authors concluded “a small, intrapericardially positioned, continuous-flow, centrifugal pump was noninferior to contemporaneously implanted, commercially available ventricular assist devices. Functional capacity and quality of life improved markedly, and the adverse event profile was favorable.”

**Destination Therapy: Left Ventricular Assist Device**

LVADs as destination therapy based on the 2002 Blue Cross and Blue Shield Association TEC assessment offers the following observations and conclusions:

- The available evidence comes from a single, well-designed and rigorously conducted randomized trial, known as the REMATCH study. (24) The study was a cooperative effort of Thoratec, Columbia University, and the National Institutes of Health.
The randomized trial found that patients with end-stage heart failure who are not candidates for cardiac transplantation have significantly better survival on a VAD compared with treatment by optimal medical therapy. Median survival was improved by approximately 8.5 months. Serious adverse events were more common in the VAD group, but these appear to be outweighed by this group’s better outcomes on function; New York Heart Association (NYHA) class was significantly improved, as was quality of life among those living to 12 months.

VAD patients spend a greater relative proportion of time inside the hospital than medical management patients do, but the survival advantage would mean a longer absolute time outside the hospital.

Park and colleagues published an extended 2-year follow-up of patients in the REMATCH trial, which found that survival and quality-of-life benefits were still apparent. In addition, this study and other case series suggest continuing improvement in outcomes related to ongoing improvements in the device and in patient management. (2, 25)

Percutaneous Ventricular Assist Devices (pVAD) aka Paracorporeal Alternative to intra-aortic balloon pump (IABP) in cardiogenic shock: Three randomized controlled trials (RCTs) have been published that compare percutaneous ventricular assist device (pVAD) to IABP for patients with cardiogenic shock, (26-28) along with a systematic review and meta-analysis of these 3 trials. (29) The meta-analysis was published in 2009 by Chen et al. The 3 RCTs enrolled a total of 100 patients, 53 treated with a pVAD and 47 treated with an IABP. All three study populations included patients with acute myocardial infarction (MI) and cardiovascular shock; one of the trials (30) restricted this population to patients who were post revascularization in the acute MI setting. The primary outcomes reported were 30-day mortality, hemodynamic measures of left ventricular (LV) pump function, and adverse events.

None of the 3 trials reported an improvement in mortality associated with pVAD use. The combined analysis estimated the relative risk for death in pVAD patients as 1.06 (95% CI: 0.68-1.66, p=0.80). All 3 trials reported an improvement in LV hemodynamics in the pVAD group. On combined analysis, there was a mean increase in cardiac index of 0.35 L/min/m² for
the pVAD group, an increase in mean arterial pressure of 12.8 mm Hg (95% CI: 3.6-22.0, p<0.001), and a decrease in pulmonary capillary wedge pressure of 5.3 mm Hg (95% CI: 1.2-9.4, p<0.05). Complications were more common in the pVAD group. On combined analysis, patients in the pVAD group had a significantly increased likelihood of bleeding events with a relative risk of 2.35 (95% CI: 1.40-3.93). Leg ischemia was also more common in the pVAD group, but this difference did not meet statistical significance (relative risk [RR]: 2.59, 95% CI: 0.75-8.97, p=0.13).

Cardiogenic Shock Refractory to IABP: Case series of patients with cardiogenic shock refractory to IABP who were treated with pVAD have also been published. In the largest series, Kar et al. (31) treated 117 patients who had severe, refractory cardiogenic shock with the TandemHeart® System. Eighty patients had ischemic cardiomyopathy and 37 had nonischemic cardiomyopathy. There were significant improvements in all hemodynamic measures following LVAD placement. For example, cardiac index increased from 0.52±0.8 L/min/m² to 3.0±0.9 L/min/m² (p<0.001), and the systolic blood pressure (BP) increased from 75±15 mm Hg to 100±15 mm Hg (p<0.001). Complications were common post-LVAD implantation. Thirty-four patients had bleeding around the cannula site (29.1%) and 35 developed sepsis during the hospitalization (29.9%). Groin hematoma occurred in 6 patients (5.1%); limb ischemia in 4 patients (3.4%); femoral artery dissection or perforation in 2 patients (1.7%); stroke in 8 patients (6.8%); coagulopathy in 13 patients (11.0%).

High-Risk Patients Undergoing Invasive Cardiovascular Procedures: The PROTECT trial intended to evaluate whether the Impella® 2.5 system improved outcomes for patients undergoing high-risk percutaneous coronary intervention (PCI) procedures. PROTECT I (32) was a feasibility study of 20 patients who had left main disease or last patent coronary conduit that required revascularization but who were not candidates for coronary artery bypass graft (CABG) surgery. High-risk PCI was performed using the Impella® system for circulatory support. All of the procedures were completed successfully without any hemodynamic compromise during the procedures. There were 2 patient deaths within 30 days (10%) and 2 patients had a periprocedural MI (10%). An additional 2 patients had evidence of hemolysis, which was transient and resolved without sequelae.
The PROTECT II trial was planned as an RCT to compare the Impella® system with IABP in patients undergoing high-risk PCI procedures. Enrollment was planned for 654 patients from 50 clinical centers. The primary endpoint was the composite of 10 different complications occurring within 40 days of the procedure, with the authors hypothesizing a 10% absolute decrease in the complication rate for patients in the pVAD group. The trial was discontinued prematurely in late 2010 due to futility, after an interim analysis revealed that the primary endpoint could not be reached. At this point, approximately half the planned patients had been enrolled. Interim results were presented at the 2011 American College of Cardiology (ACC) scientific meeting. (33) These results reported composite adverse event rates of 38% in the pVAD group compared to 43% in the IABP group (p=0.40).

A few other case series have described pVAD use in high-risk patients undergoing an invasive cardiac procedure. Sjauw et al. (34) performed a retrospective analysis of 144 consecutive patients undergoing high-risk PCI with pVAD support (Impella® system) from a European registry. Endpoints included successful device function and incidence of adverse events at 30 days. The device was successfully implanted in all 144 patients. There was one periprocedural death and 8 deaths at 30 days for a mortality rate of 5.5%. Bleeding requiring transfusion or surgery occurred in 6.2% of patients, and vascular access site complications occurred in 4.0%. There was one stroke (0.7%) and no MIs were reported.

Kar et al. (35) reported on 5 patients who were treated with pVAD support during PCI. All patients were ineligible for CABG because of severe comorbidities. In 4 of 5 patients, the procedure was performed successfully and the pVAD removed within several hours. In the fifth patient, persistent cardiogenic shock precluded removal of the pVAD for more than 48 hours and the patient eventually died of progressive heart failure 10 days after pVAD was discontinued. Giombolini et al. (36) treated 6 patients with pVAD who were undergoing a high-risk cardiac procedure. Three cases were performed on an emergency basis and 3 were performed on an elective basis. There were no deaths, and all 6 procedures were successfully completed.
Practice Guidelines and Position Statements

The American College of Cardiology/American Heart Association (ACC/AHA) released a 2009 focused revision to the 2005 guideline to the management of end-stage heart failure. (37) The ACC/AHA 2005 guideline remained unchanged in regards to LVADs:

- Consideration of an LV assist device as permanent or “destination” therapy is reasonable in highly selected patients with refractory end-stage HF and an estimated 1-year mortality over 50% with medical therapy (Level of Evidence: B)

The Heart Failure Society of America published guidelines in 2010 on surgical approaches to the treatment of heart failure. (39) The following recommendations were made regarding left ventricular assist devices:

- Patients awaiting heart transplantation who have become refractory to all means of medical circulatory support should be considered for a mechanical support device as a bridge to transplant. (Strength of Evidence = B)

- Permanent mechanical assistance using an implantable assist device may be considered in highly selected patients with severe HF [heart failure] refractory to conventional therapy who are not candidates for heart transplantation, particularly those who cannot be weaned from intravenous inotropic support at an experienced HF center. (Strength of Evidence = B)

- Patients with refractory HF and hemodynamic instability, and/or compromised end-organ function, with relative contraindications to cardiac transplantation or permanent mechanical circulatory assistance expected to improve with time or restoration of an improved hemodynamic profile should be considered for urgent mechanical circulatory support as a "bridge to decision." These patients should be referred to a center with expertise in the management of patients with advanced HF. (Strength of Evidence = C)

The European Society of Cardiology published guidelines in 2008 for the diagnosis and treatment of acute and chronic heart failure. (20) A focused update was published in 2010. (39)
These guidelines included the following statements about LVADs:

- Current indications for LVADs include bridging to transplantation and managing patients with acute, severe myocarditis (Class IIa recommendation, level of evidence C).
- LVAD may be considered as destination therapy to reduce mortality in patients with severe heart failure who are ineligible for transplant. (Class IIb recommendation, level of evidence B).

**Summary**

There are some small observational studies that provide some evidence that hemodynamic support in the immediate cardiac postoperative period utilizing implantable ventricular assist devices may be beneficial in a select group of patients. Therefore, 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. There is a growing body of evidence from several clinical trials supporting implantable ventricular assist devices as a bridge to transplant, possibly improving mortality as well as quality of life, therefore, 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 aged 5 to 16 years 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.

A well-designed clinical trial, with 2 years of follow-up data, demonstrates an advantage of implantable ventricular assist devices as destination therapy for patients who are ineligible for heart transplant. Despite an increase in adverse events, both mortality and quality of life appear to be improved for these patients. As destination therapy, implantable ventricular assist
devices with FDA approval or clearance may be considered **medically necessary** with end-stage heart failure patients who are ineligible for human heart transplant and who meet the following "REMATCH Study" criteria and not meet one of these criteria; 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.

All other applications of implantable ventricular devices are considered **not medically necessary**.

The use of non-FDA approved or cleared implantable ventricular assist devices is considered **investigational**.

The evidence on percutaneous ventricular assist devices (pVADs) do not support that these devices improve health outcomes. Three randomized controlled trials of pVAD versus intra-aortic balloon pump (IABP) for patients in cardiogenic shock failed to demonstrate a mortality benefit and reported higher complications associated with pVAD use. A moderately large RCT of pVAD support versus usual care in patients undergoing high risk PCI procedures was terminated early due to futility. Case studies of patients with cardiogenic shock refractory to IABP have reported improved hemodynamic parameters following pVAD. However these uncontrolled studies cannot determine if pVAD improves mortality and high rates of complications are reported with pVAD use. Because of the lack of demonstrated benefits in high quality trials, the high complication rates reported, and lack of support that these devices improve health outcome, the use of the pVADs for all indications is considered **not medically necessary**.

**Medicare National Policy**

Post-cardiotomy is the period following open-heart surgery. VADs used for support of blood circulation post-cardiotomy are covered only if they have received approval from the Food and Drug Administration (FDA) for that purpose, and the VADs are used according to the FDA-approved labeling instructions.

Medicare has a national coverage policy regarding bridge-to-transplant LVADs, mandating coverage for the following conditions:

- The VAD is used according to FDA labeling;
The patient is approved and listed as a heart transplant candidate; and

The VAD is implanted in a Medicare-approved heart transplant center or has received written permission from the Medicare-approved heart transplant center under which the patient is listed prior to implantation of the VAD.

Medicare also has an affirmative national coverage decision regarding VADs as destination therapy when performed at a Medicare VAD destination-approved facility:

The VADs are covered for patients who have chronic end-stage heart failure (New York Heart Association Class IV end-stage left ventricular failure for at least 90 days with a life expectancy of less than 2 years), are not candidates for heart transplantation, and meet all of the following conditions:

a. The patient’s Class IV heart failure symptoms have failed to respond to optimal medical management, including dietary salt restriction, diuretics, digitalis, beta-blockers, and ACE [angiotensin-converting enzyme] inhibitors (if tolerated) for at least 60 of the last 90 days;

b. The patient has a left ventricular ejection fraction (LVEF) of less than 25%;

c. The patient has demonstrated functional limitation with a peak oxygen consumption of less than 12 mL/kg/min; or the patient has a continued need for intravenous inotropic therapy owing to symptomatic hypotension, decreasing renal function, or worsening pulmonary congestion; and

d. The patient has the appropriate body size (greater than 1.5 m²) to support the VAD implantation.

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**Keywords**

Assist Devices, Ventricular Devices, Ventricular Assist, as a Bridge to Heart Transplantation Ventricular Assist Devices as a Bridge to Heart Transplantation Percutaneous Ventricular assistive device LVAD pLVAD pVAD

This policy was approved by the FEP Pharmacy and Therapeutics Committee on September 13, 2012 and is effective November 1, 2012.

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