Implantable Ventricular Assist Devices and Total Artificial Hearts

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Original Effective Date: 05/21/1999
Line(s) of Business: PPO; HMO; QUEST
Current Effective Date: 12/01/2013
Section: Surgery
Place(s) of Service: Inpatient

I. 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.

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
Implantable ventricular assist devices (pVADs). 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 (pVADs). The pVADs are placed through the femoral artery. Two different pVADs have been developed, the TandemHeart and the Impella device. 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.

II. Criteria/Guidelines

A. Implantable ventricular assist devices with FDA approval or clearance are covered (subject to Limitations/Exclusions and Administrative Guidelines) 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.

B. Implantable ventricular assist devices with FDA approval or clearance, including humanitarian device exemptions are covered (subject to Limitations/Exclusions and Administrative Guidelines) 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.

C. Total artificial hearts with FDA-approved devices are covered (subject to Limitations/Exclusions and Administrative Guidelines) as a bridge to heart transplantation for patients with biventricular failure under the following conditions:

   1. The patient has no other reasonable medical or surgical treatment options e.g., inotropes, intra-aortic balloon pumps (IABP).
   2. The patient is ineligible for other univentricular or biventricular support devices.
   3. The patient is currently listed as a heart transplantation candidate or is undergoing evaluation to determine candidacy for heart transplantation, and not expected to survive until a donor heart can be obtained.

D. Implantable ventricular assist devices are covered (subject to Limitations/Exclusions and Administrative Guidelines) in the post-cardiotomy setting in patients who are unable to be weaned off cardiopulmonary bypass.
E. Implantable ventricular assist devices with FDA approval or clearance are covered (subject to Limitations/Exclusions and Administrative Guidelines) as destination therapy for patients with end-stage heart failure who are ineligible for human heart transplant and who meet the following criteria:

1. New York Heart Association (NYHA) class IV symptoms for at least 60 days; OR
2. NYHA class III/IV for 28 days, received at least 14 days of support with IABP or dependent on IV inotropic agents, with two failed weaning attempts.
3. In addition, patients must not be candidates for human heart transplant for one or more of the following reasons:
   a. Age > 65 years; OR
   b. Insulin dependent diabetes mellitus with end-organ damage; OR
   c. Chronic renal failure (serum creatinine > 2.5 mg/dL for 90 days or more); OR
   d. Presence of other clinically significant condition.

F. For Medicare patients, see the NCD for Artificial Hearts and Related Devices (20.9) found on the CMS web site regarding eligibility requirements.

III. Limitations/Exclusions

A. Removal of the device prior to transplantation (CPT codes 33977-78) is considered part of the global fee and is incidental to the heart transplant.

B. Other applications of implantable ventricular devices or total artificial hearts are not covered, including but not limited to, the use of total artificial hearts as destination therapy because it is not known to be effective in improving health outcomes.

C. Percutaneous ventricular assist devices (pVAD) are not covered because they are not known to be effective in improving health outcomes.

IV. Administrative Guidelines

A. Precertification is not required. HMSA reserves the right to perform retrospective review using the above criteria to validate if services rendered met payment determination criteria.

B. Applicable codes:

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>33975</td>
<td>Insertion of ventricular assist device; extracorporeal, single ventricle</td>
</tr>
<tr>
<td>33976</td>
<td>;extracorporeal, biventricular</td>
</tr>
<tr>
<td>33977</td>
<td>Removal of ventricular assist device; implantable extracorporeal, single ventricle</td>
</tr>
<tr>
<td>33978</td>
<td>extracorporeal, biventricular</td>
</tr>
<tr>
<td>33979</td>
<td>Insertion of ventricular assist device; implantable intracorporeal, single ventricle</td>
</tr>
<tr>
<td>33980</td>
<td>Removal of ventricular assist device; implantable intracorporeal, single ventricle</td>
</tr>
<tr>
<td>0051T</td>
<td>Implantation of a total replacement heart system (artificial heart) with recipient</td>
</tr>
<tr>
<td>HCPCS Code</td>
<td>Description</td>
</tr>
<tr>
<td>------------</td>
<td>-------------</td>
</tr>
<tr>
<td>0052T</td>
<td>Replacement or repair of thoracic unit of a total replacement heart system (artificial heart)</td>
</tr>
<tr>
<td>0053T</td>
<td>Replacement or repair of implantable component or components of total replacement heart system (artificial heart) excluding thoracic unit</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q0480</td>
<td>Driver for use with pneumatic ventricular assist device, replacement only</td>
</tr>
<tr>
<td>Q0481</td>
<td>Microprocessor control unit for use with electric ventricular assist device, replacement only</td>
</tr>
<tr>
<td>Q0482</td>
<td>Microprocessor control unit for use with electric/pneumatic combination ventricular assist device, replacement only</td>
</tr>
<tr>
<td>Q0483</td>
<td>Monitor/display module for use with electric ventricular assist device, replacement only</td>
</tr>
<tr>
<td>Q0484</td>
<td>Monitor/display module for use with electric or electric/pneumatic ventricular assist device, replacement only</td>
</tr>
<tr>
<td>Q0485</td>
<td>Monitor control cable for use with electric ventricular assist device, replacement only</td>
</tr>
<tr>
<td>Q0486</td>
<td>Monitor control cable for use with electric/pneumatic ventricular assist device, replacement only</td>
</tr>
<tr>
<td>Q0487</td>
<td>Leads (pneumatic/electrical) for use with any type electric/pneumatic ventricular assist device, replacement only</td>
</tr>
<tr>
<td>Q0488</td>
<td>Power pack base for use with electric ventricular assist device, replacement only</td>
</tr>
<tr>
<td>Q0489</td>
<td>Power pack base for use with electric/pneumatic ventricular assist device, replacement only</td>
</tr>
<tr>
<td>Q0490</td>
<td>Emergency power source for use with electric ventricular assist device, replacement only</td>
</tr>
<tr>
<td>Q0491</td>
<td>Emergency power source for use with electric/pneumatic ventricular assist device, replacement only</td>
</tr>
<tr>
<td>Q0492</td>
<td>Emergency power supply cable for use with electric ventricular assist device, replacement only</td>
</tr>
<tr>
<td>Q0493</td>
<td>Emergency power supply cable for use with electric/pneumatic ventricular assist device, replacement only</td>
</tr>
<tr>
<td>Q0494</td>
<td>Emergency hand pump for use with electric or electric/pneumatic ventricular assist device, replacement only</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
</tr>
<tr>
<td>--------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Q0495</td>
<td>Battery/power pack charger for use with electric or electric/pneumatic ventricular assist device, replacement only</td>
</tr>
<tr>
<td>Q0496</td>
<td>Battery for use with electric or electric/pneumatic ventricular assist device, replacement only</td>
</tr>
<tr>
<td>Q0497</td>
<td>Battery clips for use with electric or electric/pneumatic ventricular assist device, replacement only</td>
</tr>
<tr>
<td>Q0498</td>
<td>Holster for use with electric or electric/pneumatic ventricular assist device, replacement only</td>
</tr>
<tr>
<td>Q0499</td>
<td>Belt/vest for use with electric or electric/pneumatic ventricular assist device, replacement only</td>
</tr>
<tr>
<td>Q0500</td>
<td>Filters for use with electric or electric/pneumatic ventricular assist device, replacement only</td>
</tr>
<tr>
<td>Q0501</td>
<td>Shower cover for use with electric or electric/pneumatic ventricular assist device, replacement only</td>
</tr>
<tr>
<td>Q0502</td>
<td>Mobility cart for pneumatic ventricular assist device, replacement only</td>
</tr>
<tr>
<td>Q0503</td>
<td>Battery for pneumatic ventricular assist device, replacement only, each</td>
</tr>
<tr>
<td>Q0504</td>
<td>Power adapter for pneumatic ventricular assist device, replacement only, vehicle type</td>
</tr>
<tr>
<td>Q0507</td>
<td>Miscellaneous supply or accessory for use with an external ventricular assist device</td>
</tr>
<tr>
<td>Q0508</td>
<td>Miscellaneous supply or accessory for use with an implanted ventricular assist device</td>
</tr>
<tr>
<td>Q0509</td>
<td>Miscellaneous supply or accessory for use with any implanted ventricular assist device for which payment was not made under Medicare part A</td>
</tr>
</tbody>
</table>

**ICD-9 Code** | **Description**                                                                 |
---|---|
398.91 | Rheumatic heart failure (congestive) |
402.01 | Hypertensive heart disease; malignant with heart failure |
402.11 | Hypertensive heart disease; benign with heart failure |
404.01 | Hypertensive heart and chronic kidney disease, malignant, with heart failure and with chronic kidney disease stage I through stage IV, or unspecified |
404.03 | Hypertensive heart and chronic kidney disease, malignant, with heart failure and with chronic kidney disease stage V or end stage renal disease |
404.11 | Hypertensive heart and chronic kidney disease, benign, with heart failure and with chronic kidney disease stage I through stage IV, or unspecified |
404.13 | Hypertensive heart and chronic kidney disease, benign, with heart failure and
### I.0 Endomyocardial fibrosis

- **ICD-9 Procedure codes**
- **Description**

<table>
<thead>
<tr>
<th>Procedure Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>37.52</td>
<td>Implantation of total internal biventricular heart replacement system (artificial heart)</td>
</tr>
<tr>
<td>37.53</td>
<td>Replacement or repair of thoracic unit of (total) replacement heart system</td>
</tr>
<tr>
<td>37.54</td>
<td>Replacement or repair of other implantable component of (total) replacement heart system</td>
</tr>
<tr>
<td>37.62</td>
<td>Insertion of temporary non-implantable extracorporeal circulatory assist device</td>
</tr>
<tr>
<td>37.63</td>
<td>Repair of heart assist system (includes replacement of parts of an existing VAD</td>
</tr>
<tr>
<td>37.65</td>
<td>Implant of single ventricular (extracorporeal) external heart assist system</td>
</tr>
<tr>
<td>37.66</td>
<td>Insertion of an implantable heart-assist system (ventricular assist device)</td>
</tr>
<tr>
<td>37.68</td>
<td>Insertion of percutaneous external heart assist device (includes pVADs)</td>
</tr>
</tbody>
</table>

### C. Codes that do not meet payment determination criteria:

<table>
<thead>
<tr>
<th>CPT</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>33990</td>
<td>Insertion of ventricular assist device, percutaneous including radiological supervision and interpretation; arterial access only</td>
</tr>
<tr>
<td>33991</td>
<td>;both arterial and venous access, with transseptal puncture</td>
</tr>
<tr>
<td>33992</td>
<td>Removal of percutaneous ventricular assist device at separate and distinct session from insertion</td>
</tr>
</tbody>
</table>

ICD-10 codes are provided for your information. These will not become effective until 10/1/2014:

<table>
<thead>
<tr>
<th>ICD-10 Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I09.81</td>
<td>Rheumatic heart failure</td>
</tr>
<tr>
<td>I11.0</td>
<td>Hypertensive heart disease with heart failure</td>
</tr>
<tr>
<td>I13.0</td>
<td>Hypertensive heart and chronic kidney disease with heart failure and stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease</td>
</tr>
<tr>
<td>ICD-10 Procedure codes</td>
<td>Description</td>
</tr>
<tr>
<td>-----------------------</td>
<td>-------------</td>
</tr>
<tr>
<td>02RK0JZ , 02RL0JZ</td>
<td>Total artificial heart is reported with a “cluster” of 2 codes for open replacement with synthetic substitute of the right and left ventricles</td>
</tr>
<tr>
<td>02HA0QZ, 02HA3QZ, 02HA4QZ</td>
<td>Surgical, heart and great vessels, insertion, heart, implantable heart assist system; open, percutaneous and percutaneous endoscopic approach codes</td>
</tr>
</tbody>
</table>
V. Rationale

LVADS as Bridge to Recovery: Post-cardiotomy Setting

Five studies of the Centrimag Right Ventricular Assist Device (RVADS) included between 12 and 32 patients, the majority of whom received biventricular devices. 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 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.

LVADS as Bridge to Transplant:

A 1996 TEC Assessment concluded that LVADs can provide an effective bridge to transplantation. Goldstein and colleagues published a more recent review. 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. 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.

In 5 reports, with samples ranging from 32 to 279 patients, most participants received the continuous-flow device as a bridge to transplantation. 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. 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. Serious adverse events occurring after HeartMate II-implantation include bleeding episodes requiring reoperation, stroke, infection, and device failure.

A systematic review published in 2012 examined the evidence on the effect of LVADs on post-transplant outcomes. This review included 31 observational studies that compared outcomes of
Implantable Ventricular Assist Devices and Total Artificial Hearts  

transplant in patients who did and did not have pre-transplant LVAD. Survival at one year was more likely in patients who had LVAD treatment, but this benefit was confined to patients who received an intra-corporeal device (relative risk [RR]: 1.8, 95% confidence interval [CI]: 1.53-2.13). For patients treated with an extracorporeal device, the likelihood of survival was not different from patients who were not treated with an LVAD (RR: 1.08, 95% CI: 0.95-1.22). There was no difference in the risk of rejection between patients who did and did not receive LVAD treatment.

There is one U.S. Food and Drug Administration (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. (19) Publications have reported positive outcomes for children using ventricular assist devices (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. 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. 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. A total of 21 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.

Conclusions. The evidence on the efficacy of LVADs as bridge to transplant consists of numerous uncontrolled trials of patients who have no other treatment options. These studies report that substantial numbers of patients survive to transplant in situations in which survival would not be otherwise expected. Despite the lack of high-quality controlled trials, this evidence is sufficient to determine that outcomes are improved in patients who have no other options for survival. The impact of pre-transplant LVADs on survival from transplant is uncertain, with some studies reporting worse survival in patients receiving LVADs, but other studies reporting similar or improved survival.

LVADS as Destination Therapy:

The policy regarding LVADs as destination therapy is based on a 2002 TEC Assessment that offered the following observations and conclusions:

- The available evidence comes from a single, well-designed and rigorously conducted randomized trial, known as the REMATCH study. 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; 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. However, the durability of the Heartmate device used in the REMATCH trial is a concern; for example, at one participating institution, all 6 long-term survivors required device change-outs. Next generation devices consisting of smaller continuous flow devices are eagerly anticipated.

Conclusions. The main piece of evidence on the efficacy of LVADs as destination therapy in patients who are not transplant candidates is from a multicenter randomized controlled trial (RCT), the REMATCH study. This trial reported that the use of LVADs led to improvements in survival, quality of life, and functional status. This evidence is sufficient to establish that health outcomes are improved for this patient population.

Total Artificial Hearts (TAH)

TAH as Bridge to Transplant:

The FDA approval of the CardioWest TAH was based on the results of a nonrandomized, prospective study of 81 patients. Patients had failed inotropic therapy and had biventricular failure and thus were not considered appropriate candidates for an LVAD. The rate of survival to transplant was 79%, which was considered comparable to the experience with LVAD in patients with left ventricular failure. The mean time from entry into the study until transplantation or death was 79.1 days.

Other case series have been reported on outcomes of the TAH as a bridge to transplant. For example, Copeland et al. reported on 101 patients treated with the SynCardia artificial heart as a bridge to transplant. All patients either met established criteria for mechanically assisted circulatory support, or were failing medical therapy on multiple inotropic drugs. The mean support time was 87 days, with a range of 1-441 days. Survival to transplant was 68.3% (69/101). Of the 32 deaths prior to transplant, 13 were due to multiple organ failure, 6 were due to pulmonary failure, and 4 were due to neurologic injury. Survival after transplant at 1, 5, and 10 years, respectively, was 76.8%, 60.5%, and 41.2%.

TAH Destination Therapy:

Data concerning the artificial heart are available from information concerning the FDA approval and from a published article describing results for the first 7 patients. The FDA indicated that their decision was based on the company’s laboratory and animal testing and on a small clinical study of 14 patients conducted by Abiomed. The patients had a 1-month survival prognosis of not more than 30%, were not eligible for cardiac transplants, and were felt to not benefit from VAD therapy.
The study was reported to show that the device is safe and has likely benefit for people with severe heart failure whose death is imminent and for whom no alternative treatments are available. Of the 14 patients in the study, 12 survived surgery. Mean duration of support for the patients was 5.3 months. In some cases, the device extended survival by several months; survival was 17 months in 1 patient. Six patients were ambulatory; 1 patient was discharged home. Complications included postoperative bleeding and neurologic events. Device-related infection was "nonexistent."

This device shows technological progress, and these initial results are encouraging; however, a number of questions remain. These questions may be answered once the results of the 14-patient study are published, or data on a larger group of patients may be needed. One issue is to further analyze relevant patient outcomes (complications, quality of life, survival, etc.). Therefore, based on current information, this device is not covered.

Conclusions. There is a smaller amount of evidence on the use of TAH as a bridge to transplantation, or as destination therapy, compared to the use of LVADs. The type of evidence on bridge to transplant is similar to that for LVADs, 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. There is insufficient evidence on the use of TAH as destination therapy to support conclusions.

Percutaneous ventricular assist devices (pVAD)

Three randomized controlled trials (RCTs) have been published that compare pVADs to IABP for patients with cardiogenic shock, along with a systematic review and meta-analysis of these 3 trials. 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 3 study populations included patients with acute myocardial infarction (MI) and cardiovascular shock; one of the trials restricted this population to patients who were postrevascularization 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).

Case series of patients treated with pVADs as an alternative to IABP in cardiogenic shock have been published, and report high success rates as a bridge to alternative therapies. However, these studies do not add much to the evidence on efficacy that is reported from the RCTs.
pVADS as Bridge to Recovery in 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. 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%).

pVADs Ancillary Support in 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 1 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. 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. 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. 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 patient eventually died of progressive heart failure 10 days after pVAD was discontinued. Giombolini et al. (39) 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.

**Conclusions.** pVADs have been tested in RCTs and uncontrolled studies of patients with cardiogenic shock and in patients undergoing high-risk cardiac interventions. The RCTs do not report a benefit for use of pVADs. In addition, both the RCTs and case series report high rates of adverse events that may outweigh any potential benefits. As a result, the evidence on pVADs does not support an improvement in health outcomes for patients with cardiogenic shock or in patients undergoing high-risk cardiac interventions.

**Ongoing trials (all devices)**

The BERLIN Heart EXCOR IDE study is a prospective multicenter, single-arm trial of the EXCOR device in small children aged 0-16 years with severe heart failure meeting the criteria for transplantation. This is the only device that is FDA-approved for children younger than 5 years of age. The primary efficacy endpoint of this trial is survival to recovery or heart transplant, and the primary safety endpoint is the incidence of serious adverse events. A total of 48 children are planned to be enrolled. The study population will be compared to historical controls treated with extra-corporeal membrane oxygenation (ECMO).

**Summary**

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. There is a substantial body of evidence from clinical trials and observational studies supporting implantable ventricular assist devices as a bridge to transplant in patients with end-stage heart failure, possibly improving mortality as well as quality of life. 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. Therefore, LVADs may be considered medically necessary as a bridge to transplant and as destination therapy in patients who are not transplant candidates.

The evidence for total artificial heart in this setting is less robust. However, given the limited evidence and the lack of medical or surgical options for these patients, TAH is likely to improve outcomes for a carefully selected population with end-stage biventricular heart who are not appropriate candidates for an LVAD. TAH may be considered medically necessary for this purpose. There is insufficient evidence on the use of TAH as destination therapy, and TAH is not covered for this purpose.
The evidence on pVADs does not support that these devices improve health outcomes. Three randomized controlled trials of pVAD versus IABP for patients in cardiogenic shock failed to demonstrate a mortality benefit and reported higher complications associated with pVAD use, and a fourth RCT was terminated early due to futility. Case series of patients with cardiogenic shock refractory to IABP have reported improved hemodynamic parameters following pVAD placement. However, these uncontrolled series 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, and the high complication rates reported, the use of pVAD for all indications is not covered.

Practice Guidelines and Position Statements

The American College of Cardiology/American Heart Association (ACC/AHA) released a guideline to the management of endstage heart failure in 2005; a 2009 focused update did not change any recommendations regarding the technologies covered in this policy. The group has stated that left ventricular assist devices may be indicated in a highly select group of patients who are not candidates for heart transplantation and are likely to have a 1-year survival rate of less than 50% with medical therapy alone. The short-term use of any form of mechanical ventricular support is mentioned as an area of research interest. No recommendations are made regarding this indication.

The Heart Failure Society of America published guidelines in 2010 on surgical approaches to the treatment of heart failure. 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. A focused update was published in 2010. These guidelines included the following statements about LVADs:

- Current indications for LVADs and artificial hearts 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).

VI. Important Reminder

The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA’s determination as to medical necessity in a given case, the physician may request that HMSA reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

VII. References


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