Percutaneous Ventricular Assist Devices

Number 7.03.11 *
Effective Date November 1, 2016
Revision Date(s) 10/11/16; 07/14/15; 07/14/14; 04/08/13; 11/13/12; 10/11/11;
11/09/10; 10/13/09; 10/14/08; 11/14/06; 07/11/06; 06/14/05;
02/10/04; 10/16/03; 04/15/03; 11/12/02; 06/27/00; 06/01/99;
04/14/98
Replaces N/A

*Medicare has a policy.

Policy

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

(Note that implantable ventricular assist devices and total artificial hearts are outside of the scope of this policy.)

Related Policies

None

Policy Guidelines

Coding

<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>
<tr>
<td>33993</td>
<td>Repositioning of percutaneous ventricular assist device with imaging guidance at separate and distinct session from insertion</td>
</tr>
<tr>
<td>33999</td>
<td>Unlisted procedure, cardiac surgery</td>
</tr>
</tbody>
</table>

Description

Background
**Percutaneous Ventricular Assist Devices (pVAD)**

Ventricular assist devices (VADs) offer mechanical support to augment cardiac output. VADs may be internal or largely external. Devices in which most 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. These circulatory assist devices are placed percutaneously (i.e., are not implanted). These may be referred to as pVADs. 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 vein 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 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, stroke, and arrhythmias.

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

**Regulatory Status**

Two percutaneous ventricular assist devices have received approval by the FDA. These devices are summarized in Table 1, and described further in following sections.

**Table 1. Available Percutaneous Ventricular Assist Devices**

<table>
<thead>
<tr>
<th>pVAD 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>Impella®</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>
<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>
</tbody>
</table>

FDA: U.S. Food and Drug Administration

**Percutaneous Ventricular Assist Devices (Circulatory Assist Devices)**

In May 2008, the Impella® Recover LP 2.5 Percutaneous Cardiac Support System (Abiomed, Aachen, Germany) was cleared for marketing by FDA through the 510(k) process for short-term (<6 hours) use in patients requiring circulatory support.

In March 2015, the Impella 2.5 System received approval through the PMA process for temporary ventricular support during high-risk percutaneous coronary interventions.

The TandemHeart® (Cardiac Assist, Pittsburgh) received a similar 510(k) approval for short-term circulatory support in September 2005. FDA product code: KFM.

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

**Scope**

Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject
to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.

### Benefit Application

N/A

### Rationale

<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individuals:</td>
<td>Interventions of interest are:</td>
<td>Comparators of interest are:</td>
<td>Relevant outcomes include:</td>
</tr>
<tr>
<td>• With cardiogenic shock</td>
<td>• Percutaneous ventricular assist device</td>
<td>• Intra-aortic balloon pump</td>
<td>• Overall survival</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Symptoms</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Morbid events</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Functional outcomes</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Quality of life</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Treatment-related mortality</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Treatment-related morbidity</td>
</tr>
<tr>
<td>Individuals:</td>
<td>Interventions of interest are:</td>
<td>Comparators of interest are:</td>
<td>Relevant outcomes include:</td>
</tr>
<tr>
<td>• Who undergo a high-risk cardiac procedures</td>
<td>• Percutaneous ventricular assist device</td>
<td>• Intra-aortic balloon pump</td>
<td>• Overall survival</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Symptoms</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Morbid events</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Functional outcomes</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Quality of life</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Treatment-related mortality</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Treatment-related morbidity</td>
</tr>
<tr>
<td>Individuals:</td>
<td>Interventions of interest are:</td>
<td>Comparators of interest are:</td>
<td>Relevant outcomes include:</td>
</tr>
<tr>
<td>• With cardiogenic shock refractory to intra-aortic balloon pump</td>
<td>• Percutaneous ventricular assist device</td>
<td>• Optimal medical therapy</td>
<td>• Overall survival</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Other mechanical circulatory support</td>
<td>• Symptoms</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Morbid events</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Functional outcomes</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Quality of life</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Treatment-related mortality</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Treatment-related morbidity</td>
</tr>
</tbody>
</table>

This policy was created in November 1996 and has been regularly updated with searches of the MEDLINE database. The most recent literature review was performed for the period up to July 11, 2016. The literature review focuses on 3 uses of these devices: (1) as an alternative to IABP in cardiogenic shock, (2) as a bridge to recovery in cardiogenic shock refractory to IABP, and (3) as ancillary support in high-risk patients undergoing invasive cardiovascular procedures. Following is a summary of the key literature to date.

**Percutaneous Ventricular Assist Devices (pVADs)**

**pVADs as an Alternative to Intra-Aortic Balloon Pump in Cardiogenic Shock**

Three RCTs have been published that compare pVADs with intra-aortic balloon pumps (IABPs) for patients with cardiogenic shock, (1-3) along with a systematic review and meta-analysis of these 3 trials. (4) The meta-analysis was published in 2009 by Cheng 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; 1 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 LV pump function, and adverse events.
None of the three 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 to 1.66; p=0.80). All three 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 to 22.0; p<0.001), and a decrease in pulmonary capillary wedge pressure of 5.3 mm Hg (95% CI: 1.2 to 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 to 3.93). Leg ischemia was also more common in the pVAD group, but this difference did not meet statistical significance (RR=2.59; 95% CI: 0.75 to 8.97; p=0.13).

Romeo et al (2016) reported on a systematic review and meta-analysis that evaluated a variety of percutaneous mechanical support methods, including pVADs, for patients with cardiogenic shock due to AMI who were undergoing revascularization.(5) This review included the 3 RCTs (described above) comparing pVADs with intra-aortic balloon pumps (IABPs), along with 3 observational studies. In the comparison of pVADs with IABP, the reviewers found that in-hospital mortality (the primary outcome of the analysis) was nonsignificantly increased in the pVAD group.

O'Neill et al. compared outcomes for patients with acute MI complicated by cardiogenic shock who received pVAD support pre- and post-PCI to those who received IABP support post-PCI - using data from 154 consecutive patients enrolled in a multicenter registry.(6) Patients who received pVAD support pre-PCI had higher survival to discharge compared with those who received pVAD support post-PCI (65.1% vs. 40.7%; p=0.003). In multivariable analysis, receiving pVAD support pre-PCI was associated with inhospital survival (odds ratio [OR], 0.37; 95% CI: 0.17 to 0.79; p=0.01). However, the potential for underlying differences in patient groups other than the use of pVAD support makes the study's implications uncertain.

Case series of patients treated with pVADs as an alternative to IABP in cardiogenic shock have been published (7-8) and report high success rates as a bridge to alternative therapies. However, given the availability of RCT evidence, these studies add a limited amount to the body of evidence on the efficacy of pVADs for the management of cardiogenic shock.

**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.(9) 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 systolic blood pressure 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**

In 2016, Briasoulis et al reported on a meta-analysis of pVAD devices as an adjunct to high-risk PCI.(10) The reviewers included RCTs and cohort studies, identifying 18 nonrandomized observational studies and 1 RCT. The single RCT identified was the PROTECT II trial described in more detail below. In the observational studies, the sample sizes ranged from 7 to 637 patients. In pooled analysis, the 30-day mortality rate following Impella-assisted high-risk PCI was 3.5% (95% CI, 2.2% to 4.8%; RR=20%), while that for TandemHeart-assisted high-risk PCI was 8% (95% CI, 2.9% to 13.1%; RR=55%). The pooled vascular complication rates were 4.9% (95% CI, 2.3% to 7.6%) and 6.5% (95% CI, 3.2% to 9.9%) for the Impella and the TandemHeart, respectively.

The PROTECT trial intended to evaluate whether the Impella® 2.5 system improved outcomes for patients undergoing high-risk PCI procedures. PROTECT I(11) 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 surgery. High-risk PCI was performed using the Impella® system for circulatory support. All of the procedures were successfully completed 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 end point was the composite of 10 different complications occurring within 30 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 of the first 327 patients enrolled revealed that the primary end point could not be reached. At the point that the data safety and monitoring board stopped the study, 452 patients had been enrolled, 3 of whom withdrew consent and 1 who died. Results were published by O’Neill et al. in 2012. The study’s primary analysis was intention to treat and included all 448 patients randomly assigned to the Impella® system (n=225) or IABP (n=223). The primary composite end point of major adverse effects at 30 days occurred in 35.1% of Impella® patients and in 40.1% of the IABP patients (p=0.277). There was no significant difference in the occurrence of in-hospital death, stroke, or MI between the Impella® patients and the IABP patients.

In a prespecified subgroup analysis of the PROTECT II trial, Kovacic et al. compared outcomes for the Impella system compared with IABP among 325 patients with 3-vessel disease with LVEF less than or equal to 30%.(13) In the 3-vessel disease subgroup, 167 subjects were randomized to PCI with Impella support and 158 to PCI with IABP support. PCI characteristics differed in that rotational atherectomy was more aggressively used in the Impella-support group, with more passes per patient (5.6 vs. 2.8, p=0.002) and more passes per coronary lesion (3.4 vs. 1.7, p=0.001). Acute procedural revascularization results did not differ between groups. At 30 days, the major adverse event rate did not differ significantly between groups (32.9% of Impella patients vs. 42.4% of IABP patients, p=0.078). At 90 days, Impella patients had a significantly lower major adverse event rate compared with IABP patients (39.5% vs. 51.0%, p=0.039). The 90-day event rates for the individual components of the composite major adverse event score differed only for severe hypotension requiring treatment, which was more common in patients treated with IABP (7.6% vs. 2.4%, p=0.029).

In a post hoc analysis, results of the PROTECT II trial were reanalyzed by Dangas et al., using a revised definition of MI in the determination of patients with major adverse events and major adverse cardiac and cerebral events. In contrast to the original trial, which used a cutoff of 3 times the upper limit of normal for biomarker elevation to define periprocedural MI, the authors used a cutoff of 8 times the upper limit of normal for biomarker elevation or the presence of Q waves to define periprocedural MI. In multivariable analysis, compared with IABP, treatment with the Impella system was associated with freedom from 90-day major adverse events (OR=0.75; 95% CI: 0.61 to 0.92; p=0.007) and major adverse cardiac and cerebral events (OR=0.76; 95% CI: 0.61 to 0.96; p=0.020).

Other case series have described pVAD use in high-risk patients undergoing an invasive cardiac procedure. Sjauw et al retrospectively analyzed 144 consecutive patients undergoing high-risk PCI with pVAD support (Impella system) from a European registry. End points included successful device function and incidence of adverse events at 30 days. The device was successfully implanted in all 144 patients. There was 1 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 1 (0.7%) stroke, and no MIs were reported. Maini et al performed a similar retrospective analysis of 175 patients undergoing high-risk PCI with pVAD support with the Impella 2.5 circulatory support system. The primary safety end point was the incidence of major adverse cardiac events at 30 days. Secondary end points included device safety and efficacy and patient outcomes at 30 days and 12 months. Angiographic revascularization was successful in 99% of patients. At 30-day follow-up, the major adverse cardiac event rate was 8%; survival was 96%, 91%, and 88% at 30 days, 6 months, and 12 months, respectively. Secondary safety end points occurring most frequently included acute renal dysfunction (2.8%), hypotension on support (3.4%), ventricular tachycardia (VT), or cardiopulmonary resuscitation (2.8%); other vascular complications included vessel dissection and arteriovenous fistula (3.4%), hematomas ipsi- or contralateral to the device insertion site (8.6%), infection (5.1%), and blood transfusion (9.7%).

Reddy et al. reported outcomes for a series of 66 patients enrolled in a prospective, multicenter registry who underwent ventricular tachycardia (VT) ablation with a pVAD or IABP.(17) Twenty-two patients underwent ablation with IABP assistance, while 44 underwent ablation with either the TandemHeart or Impella pVAD device (non-IABP group). Compared with patients who received support with an IABP, those who received support with a pVAD had greater numbers of unstable VTs that could be mapped and ablated (1.05 vs. 0.32, p<0.001), greater numbers of VTs that could be terminated by ablation (1.59 vs. 0.91, p=0.001), and fewer numbers of VTs that were terminated with rescue shocks (1.9 vs. 3.0, p=0.049). More pVAD-supported patients could undergo entrainment/activation mapping (82% vs. 59%, p=0.046). Mortality and VT recurrence did not differ over the study
follow-up period (average, 12 months).

In a retrospective study, Aryana et al. reported procedural and clinical outcomes for 68 consecutive unstable patients with scar-mediated epicardial or endocardial VT who underwent ablation with or without pVAD support. Thirty-four patients had hemodynamic support periprocedurally with a pVAD. pVAD- and non-pVAD-supported patients were similar at baseline, with no differences in procedural success rates between groups. Compared with non-pVAD-supported patients, patients in the pVAD group had a longer maximum time in unstable VT (27.4 vs. 5.3 min, p<0.001), a greater number of VT ablations per procedure (1.2 vs. 0.4, p<0.001), a shorter radiofrequency ablation time (53 vs. 68 seconds, p=0.022), and a shorter hospital length of stay (4.1 vs. 5.4 days, p=0.013). Over a follow-up period of 19 months, rates of VT recurrence did not differ between groups.

Summary of Evidence
For individuals with cardiogenic shock or who undergo a high-risk cardiac procedures who receive a percutaneous ventricular assist device (pVAD), the evidence includes randomized controlled trials (RCTs). Relevant outcomes are overall survival, symptoms, morbid events, functional outcomes, quality of life, and treatment-related mortality and morbidity. Three RCTs 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 fourth RCT comparing pVAD with IABP as an adjunct to high-risk percutaneous coronary interventions was terminated early due to futility; analysis of enrolled subjects did not demonstrate significant improvements in the pVAD group. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with cardiogenic shock refractory to IABP who receive a pVAD, the evidence includes case series. Relevant outcomes are overall survival, symptoms, morbid events, functional outcomes, quality of life, and treatment-related mortality and morbidity. Case series of patients with cardiogenic shock refractory to IABP have reported improved hemodynamic parameters following pVAD placement. However, these uncontrolled series does not provide evidence that pVADs improve mortality, and high rates of complications have been reported with pVAD use. The evidence is insufficient to determine the effects of the technology on health outcomes.

Clinical Input Received Through Physician Specialty Societies and Academic Medical Centers
While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received through 2 physician specialty societies and 5 academic medical centers while this policy was under review in May 2014. Vetting focused on the use of percutaneous VADs in accordance with the American Heart Association/American College of Cardiology guidelines (2013).

Most of those providing input considered pVADs to be investigational as a “bridge to recovery” or “bridge to decision” and for all other indications. Some reviewers noted that pVADs may improve patients’ hemodynamics better than other alternatives, such as an IABP, but are associated with more complications. Some reviewers noted that, despite a lack of evidence to indicate that pVADs improve overall outcomes, there may be cases when pVADs may be considered to support an intervention or treatment for a life-threatening condition.

Practice Guidelines and Position Statements
Society for Cardiovascular Angiography and Interventions et al
In 2015, the Society for Cardiovascular Angiography and Interventions, the Heart Failure Society of America (HFSA), the Society of Thoracic Surgeons, and the American College of Cardiology published a clinical expert consensus statement on the use of percutaneous mechanical circulatory support (MCS) devices in cardiovascular care.(19) This statement addressed IABPs, left atrial-to-aorta assist device (eg, TandemHeart), left ventricle-to-aorta assist devices (eg, Impella), extracorporeal membrane oxygenation (ECMO), and methods of right-sided support. Specific recommendations are not made, but the statement reviews the use of MCS in patients undergoing high-risk percutaneous intervention (PCI), those with cardiogenic shock, and those with acute
decompensated heart failure.

The American College of Cardiology/American Heart Association (ACC/AHA)

The American College of Cardiology Foundation and American Heart Association (ACCF/AHA) released guidelines for the management of heart failure in October 2013 that include recommendations related to the use of for mechanical circulatory support (MCS), including both durable and nondurable MCS devices. (20) The guidelines categorize pVADs and extracorporeal VADs as nondurable MCS devices. The following class IIA guidelines are made related to MCS devices:

- MCS is beneficial in carefully selected patients with stage D heart failure with reduced ejection fraction (HFrEF) in whom definitive management (e.g., cardiac transplantation) or cardiac recovery is anticipated or planned. (Level of Evidence: B)
- Nondurable MCS, including the use of percutaneous and extracorporeal VADs, is reasonable as a "bridge to recovery" or "bridge to decision" for carefully selected patients with HFrEF with acute, profound hemodynamic compromise. (Level of Evidence: B)
- Durable MCS is reasonable to prolong survival for carefully selected patients with stage D HFrEF. (Level of Evidence: B)

The AHA/ACC guidelines note: “Although optimal patient selection for MCS remains an active area of investigation, general indications for referral for MCS therapy include patients with LVEF <25% and NYHA Class III–IV functional status despite GDMT, including, when indicated, CRT, with either high predicted 1- to 2-year mortality (e.g., as suggested by markedly reduced peak oxygen consumption and clinical prognostic scores) or dependence on continuous parenteral inotropic support. Patient selection requires a multidisciplinary team of experienced advanced HF and transplantation cardiologists, cardiothoracic surgeons, nurses, and ideally, social workers and palliative care clinicians.”

In 2012, AHA published recommendations for the use of MCS. (21) These guidelines define nondurable MCS as intraballoons pumps, extracorporeal membrane oxygenation, extracorporeal VADs, and pVADs. The following recommendations were made regarding indications for use of MCS, including durable and nondurable devices:

- MCS for bridge-to-transplant indication should be considered for transplant-eligible patients with end-stage heart failure who are failing optimal medical, surgical, and/or device therapies and at high risk of dying before receiving a heart transplantation. (Class I; Level of Evidence B).
- Implantation of MCS in patients before the development of advanced heart failure is associated with better outcomes. Therefore, early referral of heart failure patients is reasonable. (Class IIa; Level of Evidence B).
- MCS with a durable, implantable device for permanent therapy or destination therapy is beneficial for patients with advanced heart failure, high 1-year mortality resulting from heart failure, and the absence of other life-limiting organ dysfunction; who are failing medical, surgical, and/or device therapies; and who are ineligible for heart transplantation. (Class I; Level of Evidence B).
- Elective rather than urgent implantation of destination therapy can be beneficial when performed after optimization of medical therapy in advanced heart failure patients who are failing medical, surgical, and/or device therapies. (Class IIa; Level of Evidence C).
  - Urgent nondurable MCS is reasonable in hemodynamically compromised heart failure patients with end-organ dysfunction and/or relative contraindications to heart transplantation/durable MCS that are expected to improve with time and restoration of an improved hemodynamic profile. (Class IIa; Level of Evidence C)
  - These patients should be referred to a center with expertise in the management of durable MCS and patients with advanced heart failure. (Class I; Level of Evidence C).
- Patients who are ineligible for heart transplantation because of pulmonary hypertension related to heart failure alone should be considered for bridge to potential transplant eligibility with durable, long-term MCS. (Class IIa; Level of Evidence B).

The Heart Failure Society of America (HFSA)

The Heart Failure Society of America published guidelines in 2010 on surgical approaches to the treatment of heart failure. (22) The following recommendations were made regarding LVADs:

- 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 (ESC)
In 2012, the European Society of Cardiology issued guidelines for the diagnosis and treatment of acute and chronic heart failure, (23) which were an update to previous guidelines published in 2008 and 2010. These guidelines make the following recommendation regarding VADs:
- An LVAD or BIVAD is recommended in selected patients with end-stage heart failure despite optimal pharmacological and device treatment and who are otherwise suitable for heart transplant, to reduce the risk of heart failure hospitalization for worsening heart failure and to reduce the risk of premature death while awaiting transplant. (Class I, Level B recommendation).
- An LVAD should be considered in highly selected patients with end-stage heart failure despite optimal pharmacological and device therapy and who are not suitable for heart transplant, but are expected to survive greater than 1 year with good functional status, to improve symptoms and to reduce the risk of heart failure hospitalization and of premature death. (Class IIa, Level B recommendation).

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
Medicare has a national coverage determination for artificial hearts and related devices, including VADS. (24)

The national coverage policy mandates coverage for VADs in the post-cardiotomy setting as long as the following conditions are met:
- The VAD has approval from FDA for post-cardiotomy support.
- The VAD is used according to the FDA-approved labeling instructions.

The national coverage policy also mandates coverage for VADs as a bridge-to-transplant as long as the following conditions are met:
- The VAD has approval from FDA for the bridge-to-transplant indication.
- The VAD is used according to the FDA-approved labeling instructions.
- The patient is approved and listed as a candidate for heart transplantation by a Medicare-approved heart transplant center.
- 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 national coverage policy mandates coverage for VADs as destination therapy as long as the following conditions are met:
- The VAD has approval from FDA for the destination therapy indication.
- Patient selection: VADs are covered 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:
  - 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 7 days, or IV inotrope-dependent for 14 days; and,
  - Have a left ventricular ejection fraction (LVEF) < 25%, and,
  - 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: As of an October 30, 2013, decision memo on a National Coverage Analysis for VADs, the Centers for Medicare & Medicaid Services (CMS) concluded that the evidence is sufficient to conclude that VADs implanted in facilities that meet certain criteria improve health outcomes. Facilities currently credentialed by the Joint Commission for placement of VADs as DT [destination therapy] may continue as Medicare-approved facilities until October 30, 2014. At the conclusion of this transition period, these facilities must be in compliance with the following criteria as determined by a credentialing organization. As of the effective date, new facilities must meet the following criteria as a condition of coverage of this procedure:

- Beneficiaries receiving VADs for DT must be managed by an explicitly identified cohesive, multidisciplinary team of medical professionals with the appropriate qualifications, training, and experience. The team embodies collaboration and dedication across medical specialties to offer optimal patient-centered care. Collectively, the team must ensure that patients and caregivers have the knowledge and support necessary to participate in shared decision making and to provide appropriate informed consent. The team members must be based at the facility and must include individuals with experience working with patients before and after placement of a VAD. The team must include, at a minimum, all of the following:
  - At least one physician with cardiothoracic surgery privileges and individual experience implanting at least 10 durable, intracorporeal, left ventricular VADs as BTT [bridge to transplant] or DT over the course of the previous 36 months with activity in the last year.
  - At least one cardiologist trained in advanced heart failure with clinical competence in medical and device-based management including VADs, and clinical competence in the management of patients before and after heart transplant.
  - A VAD program coordinator.
  - A social worker.
  - A palliative care specialist.
- Facilities must be credentialed by an organization approved by CMS.

The national coverage policy mandates coverage for artificial hearts as bridge to transplant or destination therapy when performed under coverage with evidence development when a clinical study meets the criteria outlined in the Medicare policy and addresses one of the following questions:

- Were there unique circumstances such as expertise available in a particular facility or an unusual combination of conditions in particular patients that affected their outcomes?
- What will be the average time to device failure when the device is made available to larger numbers of patients?
- Do results adequately give a reasonable indication of the full range of outcomes (both positive and negative) that might be expected from more wide spread use?

References

23. McMurray JJ, Adamopoulos S, Anker SD, et al. ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure 2012: The Task Force for the Diagnosis and Treatment of Acute and Chronic Heart Failure 2012 of the European Society of Cardiology. Developed in collaboration with the Heart Failure Association (HFA) of the ESC. Eur Heart J. Jul 2012;33(14):1787-1847. PMID 22611136
Appendix

N/A

History

<table>
<thead>
<tr>
<th>Date</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>04/14/98</td>
<td>Add to Surgery Section - New Policy</td>
</tr>
<tr>
<td>06/01/99</td>
<td>Replace policy - Policy updated to include new FDA-approved devices.</td>
</tr>
<tr>
<td>06/27/00</td>
<td>Replace policy - Scheduled review; no criteria changes.</td>
</tr>
<tr>
<td>11/12/02</td>
<td>Replace policy - Policy reviewed: Rationale section expanded, references added. Policy statement on use of VADs in patients who are not transplant candidates deleted; this topic will be addressed in a separate policy. Policy statement otherwise unchanged.</td>
</tr>
<tr>
<td>04/15/03</td>
<td>Replace policy - Policy statement revised to include 2002 TEC Assessment conclusions regarding VADs in patients who are not transplant candidates, i.e., “destination” therapy. Title changed from Ventricular Assist Devices as a Bridge to Heart Transplantation.</td>
</tr>
<tr>
<td>10/16/03</td>
<td>Replace policy - Policy statement revised to limit medically necessary indications to FDA approved devices.</td>
</tr>
<tr>
<td>02/10/04</td>
<td>Replace policy - Policy statement added regarding investigational status of total artificial hearts. Additional 2003 Category III CPT codes added.</td>
</tr>
<tr>
<td>06/14/05</td>
<td>Replace policy - Policy statement revised to indicate that a total artificial heart may be considered medically necessary as a bridge to transplant, based on FDA approval for that indication.</td>
</tr>
<tr>
<td>04/21/06</td>
<td>Codes Updated - No other changes</td>
</tr>
<tr>
<td>05/26/06</td>
<td>Scope and Disclaimer Updates - No other changes.</td>
</tr>
<tr>
<td>07/11/06</td>
<td>Replace policy - Policy updated with literature review; references added; policy statement unchanged.</td>
</tr>
<tr>
<td>11/14/06</td>
<td>Replace policy - Policy updated with FDA approval of total artificial heart. Policy statement unchanged; total artificial hearts are investigational. References added.</td>
</tr>
<tr>
<td>12/11/06</td>
<td>Codes Updated - No other changes</td>
</tr>
<tr>
<td>10/14/08</td>
<td>Replace policy - Policy updated with literature search; no change to the policy statement. Codes 37.52-37.66 added, references added.</td>
</tr>
<tr>
<td>10/13/09</td>
<td>Replace policy - Policy updated with literature search; no change to the policy statement. References added.</td>
</tr>
<tr>
<td>02/09/10</td>
<td>Codes Update - New 2010 codes added.</td>
</tr>
<tr>
<td>11/09/10</td>
<td>Replace policy - Policy updated with literature search; references 1, 10, 19, 29 and 30 added. Extensive editing completed. Policy statements revised to address only implantable VADs and total artificial hearts.</td>
</tr>
<tr>
<td>10/11/11</td>
<td>Replace policy – Policy updated with literature search. Percutaneous VADs, previously not addressed, added to policy statement as investigational. Rationale updated. References 22, 30-39, 42, 43 added. ICD-10 codes added to policy.</td>
</tr>
<tr>
<td>11/27/12</td>
<td>Replace policy - Policy updated with literature search. References 18, 27-31, 33, 40, 47. Clause added to policy statement on TAH that says “…or are undergoing evaluation to determine candidacy for heart transplantation…”</td>
</tr>
<tr>
<td>01/10/13</td>
<td>Coding update. CPT codes 0148T – 0150T deleted as of 12/31/12; codes 33990 – 33991 and 33993, effective 1/1/13, added to policy.</td>
</tr>
<tr>
<td>04/08/13</td>
<td>Replace policy. Policy statement on children amended; age range changed from 5-16 to 0-16, reflecting the approval of the BERLIN heart EXCOR device for pediatric patients aged 0-16. Code Q0505, deleted 3/13/13; this is replaced with Q0507-Q0509, new codes 4/1/13.</td>
</tr>
</tbody>
</table>
03/11/14 Coding Update. Codes 37.52 - 37.55, 37.60, and 37.62 - 37.66 were removed per ICD-10 mapping project; these codes are not utilized for adjudication of policy.

07/31/14 Annual Review. Policy updated with literature review through January, 2014 and results of clinical vetting related to the use of pVADs and the total artificial heart (TAH) as destination therapy. References 5, 6, 20, 23, 24, 27, 55 added; others renumbered/removed. Policy statements unchanged.

07/14/15 Annual Review. Policy updated with literature review through April 21, 2015; references 7-8, 27, 32, 38, 41, 50, 55, 57, 61-62, 65-66, and 70 added. Policy statements unchanged. Coding update: CPT codes 33977, 33978, 33980, 33981, 33982, 33983 and 93750, plus HCPCS Q0506 removed; they were informational only.

10/11/16 Annual Review. Policy revised to remove all information regarding Total Artificial Hearts and Implantable Ventricular Assist Devices, including removing previous references 1-56 and policy title change. Policy now addresses only Percutaneous Ventricular Assist Devices. Policy updated with literature review but no change to the policy statement regarding pVADs, which remain investigational.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2016 Premera All Rights Reserved.
Discrimination is Against the Law

Premera Blue Cross complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. Premera does not exclude people or treat them differently because of race, color, national origin, age, disability or sex.

Premera:
- Provides free aids and services to people with disabilities to communicate effectively with us, such as:
  - Qualified sign language interpreters
  - Written information in other formats (large print, audio, accessible electronic formats, other formats)
- Provides free language services to people whose primary language is not English, such as:
  - Qualified interpreters
  - Information written in other languages

If you need these services, contact the Civil Rights Coordinator.

If you believe that Premera has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Civil Rights Coordinator - Complaints and Appeals
PO Box 91102, Seattle, WA 98111
Toll free 855-332-4535, Fax 425-918-5592, TTY 800-842-5357
Email AppealsDepartmentInquiries@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue SW, Room S09F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at

Getting Help in Other Languages

This Notice has Important Information. This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost. Call 800-722-1471 (TTY: 800-842-5357).

Arabic (Amharic):
لا يوجد هذا الإشعار معلومات هامة. قد يوجد أثار الإشاعات عن بعض موضوعات هذه المعلومات في هذه الإشارة. إذا كنت تعتقد أن هذه المعلومات تتعلق ببعض الشؤون الأساسية للكبار أو أي طالب أو طالبة، يمكنك الاتصال بـ Premera Blue Cross من خلال الرقم (800-722-1471) (TTY: 800-842-5357)

Arabic (Arabic):
يحتوي هذا الإشعار معلومات هامة. قد تحتوي هذه الإحالة على معلومات عن بعض الموضوعات الهامة المتعلق بها، مثل موضوعات Premera Blue Cross. يمكنك الاتصال بـ Premera Blue Cross من خلال الرقم (800-722-1471) (TTY: 800-842-5357)

Chinese (Chinese):
本通知有重要的信息。本通知可能有关于您提交的申请或保险的重要信息。本通知内可能有重要的日期，您可能需要在截止日期前采取行动，以保留您的健康保险或费用补贴。您有权利免费在您的母语得到本通知和帮助。请拨电话 800-722-1471 (TTY: 800-842-5357).

Italiano (Italian):