Ventricular Assist Devices

Number: 0654

Policy

*Please see amendment for Pennsylvania Medicaid at the end of this CPB.

Aetna considers a Food and Drug Administration (FDA)-approved ventricular assist device (VAD)* medically necessary for any of the following FDA-approved indications:

I. As a bridge to transplant for members who are awaiting heart transplantation (see CPB 0586 - Heart Transplantation (../500_599/0586.html)) and the device has received FDA approval for a bridge to transplant indication; or

II. As destination therapy when all of the following criteria are met:

1. The device has received FDA approval for a destination therapy indication; and
2. Member has New York Heart Association (NYHA) Class IV end-stage ventricular heart failure and is not a candidate for heart transplant; and
3. Member has failed to respond to optimal medical management (including beta-blockers, and angiotensin-converting enzyme (ACE) inhibitors if tolerated) for at least 45 of the last 60 days, or has been balloon pump dependent for 7 days, or has been IV inotrope dependent

Policy History

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Review History

Definitions

Additional Information

Clinical Policy Bulletin Notes
for 14 days; and

4. Has a left ventricular ejection fraction (LVEF) less than 25 %; and

5. Has demonstrated functional limitation with a peak oxygen consumption of less than or equal to 14 ml/kg/min. (Note: This criterion may be waived in persons who are balloon pump or intravenous inotrope dependent or are otherwise unable to perform exercise stress testing).

* Note: Although the HeartWare ventricular assist device is only approved as a bridge to transplant, due to its small size, it may also be considered medically necessary as destination therapy when required due to the member’s anatomy and where criteria for destination therapy are met.

Aetna considers VADs experimental and investigational for all other indications because of insufficient evidence in the peer-reviewed literature.

Aetna considers a FDA-approved percutaneous left ventricular assist device (pVAD) (e.g., the TandemHeart and the Impella) medically necessary for the following indications:

- Providing short-term circulatory support in cardiogenic shock; or
- As an adjunct to percutaneous coronary intervention (PCI) in the following high-risk patients:
  - Persons undergoing unprotected left main or last-remaining-conduit PCI with ejection fraction less than 35 %; or
  - Persons with three vessel disease end diastolic ejection fraction less than 30 %.

Aetna considers pVADs experimental and investigational for all other indications because of insufficient evidence in the peer-reviewed literature.
Aetna considers FDA-approved pediatric VADs medically necessary when both of the following criteria are met:

- Child has documented end-stage left ventricular failure; and
- An age and size-appropriate VAD will be used until a donor heart can be obtained*.

Aetna considers pediatric VADs experimental and investigational when criteria are not met.

*Note: Current FDA-approved pediatric VADs include the Berlin Heart EXCOR Pediatric Ventricular Assist Device (for children aged 16 years or younger) and the HeartAssist 5 Pediatric Ventricular Assist Device (for children aged 5 to 16 years). The EXCOR Pediatric VAD can be used in children up to 60 kg body weight. The HeartAssist 5 Pediatric VAD can be used in children with a BSA greater than or equal to 0.7 m2 and less than 1.5 m2).

Aetna considers FDA-approved right ventricular assist devices (RVADs; e.g., the CentriMag Right Ventricular Assist System) medically necessary for temporary circulatory support when both of the following criteria are met:

- RVAD is used for up to 30 days for members in cardiogenic shock due to acute right ventricular failure; and
- Member is willing and able to be treated with heparin or an appropriate alternative anti-coagulant.

Aetna considers RVADs experimental and investigational when criteria are not met.

Aetna considers the Impella RP System medically necessary for providing circulatory assistance for up to 14 days in pediatric or adult persons with a body surface area $\geq 1.5$ m2 who develop acute right heart failure or decompensation following left ventricular assist device implantation, myocardial infarction, heart transplant, or open-heart surgery.
Aetna considers the use of mesenchymal precursor cells as adjunctive therapy in recipients of ventricular assist devices experimental and investigational because the effectiveness of this approach has not been established.

Aetna considers implantable aortic counter-pulsation ventricular assist systems (e.g., the NuPulseCV iVAS and the Symphony Heart Assist System) experimental and investigational because their effectiveness has not been established.

Also see CPB 0599 - Autologous Skeletal Myoblast/Mononuclear Bone Marrow Cell Transplantation (../500_599/0599.html).

Background
A ventricular assist device (VAD) is a mechanical pump that compensates for the diminished ability of a weakened heart by assisting or replacing the function of either the left or right ventricle. A left VAD (the most commonly used) provides blood flow throughout the body while the right VAD supports the pulmonary (lung) circulation. VADs may be utilized for individuals suffering from reversible cardiac dysfunction, to support individuals who are awaiting heart transplantation or to provide permanent circulatory support with end-stage heart failure in those who are not candidates for transplantation (known as destination therapy).

Ventricular assist devices (VADs) fall into the general category of mechanical circulatory assist devices, which also includes cardiopulmonary bypass and intra-aortic balloon pumps. There are many VADs available for use. Important characteristics of these systems include: location of the pumping chamber, the specific ventricles that are supported, the pumping mechanism and how long support is indicated (either temporary or long-term support). Typically, short-term devices are extracorporeal (located outside the body) and long-term use are implantable systems.
There are several different types of VADs currently in use; the devices can be broadly subdivided into centrifugal or pulsatile pumps. Centrifugal pumps operate on the principle of a cyclone. Blood is diverted through cannulae placed in the right or left heart to an external chamber with a centrifugal pump. Centrifugal pumps include the Biopump, the Sarns-3M and the Hemopump.

Pulsatile pumps are subdivided into pneumatic and electromechanical types. Each type can be operated in several different modes including a synchronous mode triggered by the EKG (similar to an intra-aortic balloon pump) and an asynchronous mode. Placement of the inflow and outflow cannulae is variable. According to expert consensus, it is usually preferable to cannulate the left atrium because it is technically easier and spares the ventricle further injury. However, flow rates are improved with ventricular cannulation and in patients awaiting transplant, injury to the myocardium is not a concern. Pulsatile pumps include the Abiomed, Thoratec (Pierce Donachy), Novacor and HeartMate devices.

There is a small subset of patients who experience reversible heart failure after open heart surgery despite maximal support with proper volume loading, drug therapy and an intra-aortic balloon pump. The etiology of the heart failure in these patients is hypothesized to be related to "stunned" myocardium. Ventricular assist devices have been used as a method of short-term support in these patients. Several clinical studies have demonstrated that a substantial proportion of patients with post-cardiotomy cardiogenic shock can be successfully treated with a VAD, subsequently weaned from the device, and discharged home.

Ventricular assist devices have also been used as a bridge to transplant. Several clinical studies have demonstrated the success of VADs in improving survival rates to heart transplantation. In addition, VADs have been shown to significantly improve patients' functional status prior to heart transplantation such that patients are overall better surgical
candidates.

The Centers for Medicare & Medicaid Services (CMS) has published a decision memorandum liberalizing criteria for coverage of ventricular assist devices (CMS, 2010). The CMS policy removes body size criteria and eases restrictions around the required duration of failed medical therapy and peak oxygen consumption. Under the rule changes, CMS will reimburse ventricular assist devices as destination therapy when all of the following criteria are met:

I. The device to be implanted has received FDA approval for a destination therapy indication; and
II. Patient has New York Heart Association (NYHA) Class IV end-stage ventricular heart failure and is not suitable for heart transplantation; and
III. Patient has failed to respond to optimal medical management (including beta-blockers, and angiotensin-converting enzyme (ACE) inhibitors if tolerated) for at least 45 of the last 60 days (down from 60 of the prior 90 days in the earlier criteria), or patient has been balloon pump dependent for 7 days, or patient has been IV inotrope dependent for 14 days; and
IV. Patient has a left ventricular ejection fraction (LVEF) less than 25 %; and
V. Patient has demonstrated functional limitation with a peak oxygen consumption of less than or equal to 14 ml/kg/min (increased from 12 ml/kg/min in the previous criteria).

The CMS removed the previous requirement that patients must have a body size greater than 1.5 m2 because ventricular assist devices have become smaller and more portable.

The CMS rejected a proposal to expand coverage to include Class IIIb patients. The CMS decision memorandum explained that, although Class IIIb patients were included in the pivotal trial of destination therapy with the Thoratec HeartMate II ventricular assist device, they accounted for only about 20 % of the population and there were no published results specific to
that subgroup, the CMS decision memo noted. Moreover, Class IIIb as a subclassification is not widely accepted, and such patients might not be possible to identify accurately enough in routine clinical practice, according to the memo.

The U.S. Food and Drug Administration (FDA) approved VADs include, but may not be limited to, the following:

- **Bridge to transplant**: Abiomed AB5000, HeartMate II, HeartMate II LVAS, HeartMate IP, HeartMate SNAP VE LVAS, HeartMate VE LVAS, HeartMate XVE LVAS, HeartWare VAS, Novacor LVAS, Thoratec IVAD, Thoratec VAD System
- **Destination therapy**: AbioMed BVS5000, HeartMate II, HeartMate SNAP-VE LVAS, HeartMate XVE LVAS
- **Pediatric bridge to transplant**: EXCOR Pediatric VAD, HeartAssist 5 Pediatric VAD (formerly known as DeBakey VAD Child)
- **Short-term bridge to recovery**: AbioMed AB5000, AbioMed BVS5000, Thoratec IVAD, Thoratec VAD System

The U.S. Food and Drug Administration (FDA) has approved the HeartMate SNAP-VE Left Ventricular Assist System (LVAS) (Thoratec Corporation) as a long-term permanent implant (destination therapy) for end-stage heart failure patients who are not eligible for heart transplantation. In addition to use as a bridge to transplant for cardiac transplant candidates, the FDA product labeling for the HeartMate states that the device is indicated for use in patients with NYHA Class IV end-stage left ventricular failure who have received optimal medical therapy for at least 60 of the last 90 days and who have a life expectancy of less than 2 years and who are not candidates for cardiac transplantation (e.g., old age, insulin-dependent diabetes with organ damage, chronic kidney dysfunction, or other factors, such as cancer, obesity, etc. that would eliminate heart transplantation as a treatment option). The FDA approval was based on the results of the REMATCH trial, a multicenter randomized controlled clinical trial comparing permanent implantation of a HeartMate left ventricular assist device (LVAD) to maximum medical therapy in 129 adults with end-stage...
heart failure who because of their age or co-morbidities were not eligible for a heart transplant (Rose et al, 2001). To be eligible for study participation, patients had to have NYHA class IV heart failure for at least 90 days despite attempted therapy with an ACE inhibitor, diuretics, and digoxin; an ejection fraction less than or equal to 25%; and an exercise peak O2 uptake less than or equal to 12 ml/kg/min or a continued need for intravenous inotropic therapy because of symptomatic hypotension, decreasing renal function, or worsening pulmonary congestion. After 18 months of enrollment, entry criteria were relaxed to include patients with symptoms of NYHA class III or IV heart failure for 28 days and 14 days of support with an intra-aortic balloon pump or with a dependence on intravenous inotropic agents with 2 failed weaning attempts. Survival was significantly improved from 25 % at 1 year in the medical therapy group to 52 % in the LVAD group (relative risk, 0.52 (95 % confidence interval [CI]: 0.34 to 0.78)). Median length of survival for patients implanted with the HeartMate LVAD was 408 days compared to 108 days for patients in the medical therapy group. However, only 23 % of LVAD patients survived to 2 years (compared to 8 % in the medical group) (p = 0.09), and serious adverse events were 2.35 times as frequent in the LVAD group, predominately caused by infection, bleeding, neurological dysfunction, and device malfunction.

In a prospective cohort study, Shuhaiber and colleagues (2010) examined the influence of the pre-operative placement of a LVAD on survival following heart transplantation. A total of 2,786 adults aged 18 or older in status 1A or 1B (highest priority for heart transplantation with either some form of VAD, intravenous inotrope, or life expectancy of less than 7 days) were included in the study, based on the United Network for Organ Sharing Registry, 1996 to 2004. Main outcome measure was survival after heart transplantation in patients who did and did not receive a LVAD. The LVAD was not associated with decreased survival, even after the data were stratified by propensity score (the odds of being a treated patient). Inspection of the strata showed no difference in survival
between patients who received the device and those who did not. The hazard ratios in strata 1 to 5 were 0.69, 1.37, 1.55, 0.75, and 1.19, respectively, and none was statistically significant. The authors concluded that overall, survival after heart transplantation in patients who received a LVAD before transplantation was comparable to those who did not receive the device.

Kormos and associates (2010) evaluated the incidence, risk factors, and effect on outcomes of right ventricular failure in a large population of patients implanted with continuous-flow LVADs. Patients (n = 484) enrolled in the HeartMate II LVAD (Thoratec, Pleasanton, CA) bridge-to-transplantation clinical trial were examined for the occurrence of right ventricular failure. Right ventricular failure was defined as requiring a right ventricular assist device, 14 or more days of inotropic support after implantation, and/or inotropic support starting more than 14 days after implantation. Demographics, along with clinical, laboratory, and hemodynamic data, were compared between patients with and without right ventricular failure, and risk factors were identified. Overall, 30 (6 %) patients receiving LVADs required a right ventricular assist device, 35 (7 %) required extended inotropes, and 33 (7 %) required late inotropes. A significantly greater percentage of patients without right ventricular failure survived to transplantation, recovery, or ongoing device support at 180 days compared with patients with right ventricular failure (89 % versus 71 %, p < 0.001). Multi-variate analysis revealed that a central venous pressure/pulmonary capillary wedge pressure ratio of greater than 0.63 (odds ratio, 2.3; 95 % CI: 1.2 to 4.3; p = 0.009), need for pre-operative ventilator support (odds ratio, 5.5; 95 % CI: 2.3 to 13.2; p < 0.001), and blood urea nitrogen level of greater than 39 mg/dL (odds ratio, 2.1; 95 % CI: 1.1 to 4.1; p = 0.02) were independent predictors of right ventricular failure after LVAD implantation. The authors concluded that the incidence of right ventricular failure in patients with a HeartMate II ventricular assist device is comparable or less than that of patients with pulsatile-flow devices. Its occurrence is associated with worse outcomes than seen in patients without
right ventricular failure. Patients at risk for right ventricular failure might benefit from pre-operative optimization of right heart function or planned biventricular support.

Percutaneous ventricular assist devices (pVADs) are utilized for short-term bridge to recovery. Examples of pVADs include, but may not be limited to, the following: Impella 2.5 System; Impella 5.0 Percutaneous Cardiac Support System; Impella CP (Cardiac Power); Impella Recover LP 2.5; and TandemHeart PTVA System. pVADs differ from other types of VADs as they are able to be placed via cardiac catheterization without the need for open-chest surgery and use a trans-septal approach to the left ventricle (the catheter is advanced across the intra-atrial septum into the left atrium), which avoids potential difficulties in crossing the aortic valve.

The TandemHeart, a percutaneous transseptal ventricular assist (PTVA) device, is an external blood pump that provides temporary hemodynamic support to a weakened heart. It is used for critically ill patients who have sustained a massive myocardial infarction or sudden heart failure and do not have enough blood flow to support their organs. The TandemHeart augments left ventricular (LV) contractility, enhancing blood flow until the patient’s condition becomes more stable or the patient is strong enough to undergo an interventional procedure (e.g., angioplasty). In potential heart transplant patients or patients awaiting a mechanical heart assist device, the TandemHeart is considered a "bridge" giving patients extra time for the weaken heart to rest.

Rajdev et al (2008) stated that patients with multi-vessel disease, left main coronary artery (LMCA) disease or left main equivalent and/or moderate-to-severe LV dysfunction with elevated LV end-diastolic pressure are at increased risk of complications during percutaneous coronary intervention (PCI). The TandemHeart is a non-pulsatile PTVA that offers vital short-term circulatory support during high-risk PCI. These investigators assessed the feasibility and safety of implanting a
prophylactic LVAD prior to high-risk PCI and evaluated the impact of suture-mediated pre-closure of the arteriotomy site on minimizing vascular complications. Between April 2004 and November 2005, the TandemHeart was implanted in 20 patients undergoing high-risk PCI; 8 patients underwent unprotected LMCA stenting, and rotational atherectomy was used in 17 patients. Suture-mediated femoral artery pre-closure was performed prior to inserting a large-bore arterial cannula. The TandemHeart was successfully implanted in all 20 patients. Mean LV ejection fraction of subjects was 38 +/- 18%. Time-to-implantation of the TandemHeart, duration of hemodynamic support, as well as mean flow of the TandemHeart device were 31 +/- 9 mins, 74 +/- 40 mins, and 2.5 +/- 1.3 L/min, respectively. At the end of PCI, the TandemHeart was removed in all cases and sutures were deployed in 18/20 (90%) patients. There was only 1 minor vascular complication, and the average length of stay was 2 +/- 1 days. Peri-procedural and in-hospital mortality was 0%. The authors concluded that implantation of the TandemHeart PTVA device was safe and feasible in patients undergoing high-risk PCI with excellent hemodynamic support. Application of suture-mediated devices prior to large arteriotomies can significantly reduce the incidence of vascular complications.

Vranckx and colleagues (2008) reported their 6-year experience with the TandemHeart. Between September 2000 to July 2006, this device supported the circulation of 23 patients (mean age of 59 years, range of 46 to 74) who were admitted for high-risk (either emergency or elective) PCI. Successful implantation was achieved in 100% of patients. The mean time for implementation of circulatory support was 35 mins (range of 16 to 62). The index PCI was successful in all patients except 2. A pump flow up to 4L/min was achieved with significant reduction of LV filling pressures, pulmonary capillary wedge pressure, and with significant increase of systemic arterial pressures. Duration of support ranged from 1 to 222 hrs (mean of 31 +/- 49.8). Five patients died with the TandemHeart in place, 4 of whom were in irreversible cardiogenic shock at admission. Mild-to-moderate access site bleeding was seen in
27% of patients. One patient experienced a loge syndrome of the leg. Core temperature (Ct) decreased to less than 36.5 degrees C in 6 patients, profound hypothermia (Ct less than 35 degrees C) was observed in 2 patients. There was no technical device failure. The authors concluded that the TandemHeart provides effective, total LV support in very high-risk PCI settings. The rate of device-related cardiac and vascular complications was acceptable.

Al-Husami et al (2008) described their experience of patients, from December 2005 through May 2007 who underwent PCI with severely depressed LV systolic function and complex coronary lesions. The complex coronary lesions included multiple vessel coronary artery disease, left main (LM) coronary artery disease, calcified coronary lesions and bypass graft disease. All patients were clinically assessed to be at too high of a risk for circulatory collapse without maximal hemodynamic support while they underwent high-risk PCI. The TandemHeart PTVA device may be able to provide the necessary circulatory support needed to enhance procedural success and patient safety during high-risk PCI. These investigators implanted the TandemHeart PTVA device in 6 patients who underwent high-risk PCI. There was unanimity among several physicians in the authors' institution that each patient was an exceptionally high-risk for circulatory collapse due to the anticipated procedural complexity. The average ejection fraction was 33% (range of 15 to 65%); 5 of the patients were considered to be at an unacceptably high-risk for coronary artery bypass surgery. All 6 patients underwent multi-vessel PCI -- 5 underwent unprotected LM PCI; 1 of the 5 underwent vein-graft PCI as well as a debulking procedure with rotational atherectomy and PCI of the LM. These researchers had a 100% success rate with implantation of the TandemHeart PTVA device. Five of the 6 patients were alive at 30 days post-procedure. One patient died 3 days after the procedure due to multi-organ failure. A vascular surgeon performed the removal of the devices with no associated complications. The authors concluded that these findings demonstrated that hemodynamic support could be achieved safely, efficiently and
effectively by the TandemHeart PTVA device in anticipation of high-risk PCI.

The Impella LP is a percutaneous ventricular assist device that consists of a catheter which is passed retrograde through the aortic valve into the left ventricle. Via a small rotary pump located at the distal tip, it aspirates blood and delivers it into the ascending aorta. The Impella Recover LP 2.5, a percutaneous LVAD, is an intra-vascular micro-axial blood pump designed for short-term circulatory support in conditions characterized by profoundly reduced ventricular function. It provides up to 2.5 L/min forward flow from the LV into the systemic circulation. The Impella 5.0 is mainly used to manage acute life-threatening left ventricular failure, to bridge to recovery, or to bridge to a left ventricle assist device or heart transplant. Maximum flow is 5.0 L/min.

Vecchio and colleagues (2008) evaluated the feasibility, safety and efficacy of the Impella Recover LP 2.5 LVAD in patients with cardiogenic shock or undergoing high-risk PCI. A total of 11 patients presenting cardiogenic shock (n = 6) or scheduled for high-risk percutaneous re-vascularization (n = 5) were evaluated. The Impella pump was successfully implanted in all patients, except one. When implanted, the device was correctly positioned in the LV and remained in a stable position. Bleedings occurred in 7 patients (5 of them presented cardiogenic shock), while renal failure and severe thrombocytopenia were observed in 4 and 1 patients, respectively, all with cardiogenic shock. During high-risk procedures, the Impella pump succeeded in obtaining hemodynamic stability, while in only 2 patients with cardiogenic shock the device determined a significant improvement of hemodynamic variables. All elective patients and 2 patients with cardiogenic shock were discharged from the hospital and were still alive at 30-day follow-up. The authors concluded that these data, although preliminary due to the limited sample size, demonstrated the feasibility, safety and efficacy of the Impella Recover LP 2.5 during high-risk PCIs, even though the benefits of prophylactic deployment of such a system have to be further
investigated. The use of Impella Recover LP 2.5 in patients with cardiogenic shock is feasible and safe, however it maybe insufficient in reversing an advanced cardiogenic shock which, probably, has to be treated with more powerful LVADs.

Lam and associates (2009) noted that circulatory support during PCI in patients with ST-element elevation myocardial infarction (STEMI) aims at maintaining hemodynamic stability and organ perfusion. However, continuous flow pumps may interfere with the normal pulsatile circulation and the microcirculatory function. Sidestream dark field (SDF) imaging allows the visualization of microvascular structure and function of tissue and may provide information regarding the efficacy of the circulatory support. Sidestream dark field was used to study the sublingual microcirculation (MC) in 6 anterior STEMI patients treated with PCI; 3 patients received the Impella LP 2.5 device (Impella group) and 3 patients received no support (control group). Microcirculation was assessed at baseline, at 24, 48 and 72 hrs after PCI. Data were analyzed using a validated scoring method and the microvascular flow index (MFI) and perfused vessel density (PVD) were calculated. Microcirculation of 3 healthy controls was used as normalized standard. Normal MC depending on both functional capillary density (PVD) and flow velocity or quality (MFI), as observed in healthy controls, was only achieved in the Impella group and paralleled improvement in LV function. Functional capillary density in the control and Impella groups were equal and above the level of healthy controls, respectively. The quality of microcirculatory flow reached values of healthy controls only in the Impella group. The authors concluded that MC assessed by SDF improved in STEMI patients treated with the Impella LP 2.5 device to levels observed in healthy persons and remained sub-optimal after 72 hrs in patients without support.

In a prospective, multi-center study, Dixon and associates (2009) assessed the safety and feasibility of the Impella 2.5 system in patients undergoing high-risk PCI. A total of 20 patients who underwent high-risk PCI with minimally invasive circulatory support employing the Impella 2.5 system were
included in this study. All patients had poor LV function (ejection fraction less than or equal to 35%) and underwent PCI on an unprotected LMCA or last patent coronary conduit. Patients with recent ST-segment elevation myocardial infarction or cardiogenic shock were excluded. The primary safety end point was the incidence of major adverse cardiac events at 30 days. The primary efficacy end point was freedom from hemodynamic compromise during PCI (defined as a decrease in mean arterial pressure below 60 mmHg for greater than 10 mins). The Impella 2.5 device was implanted successfully in all patients. The mean duration of circulatory support was 1.7 +/- 0.6 hrs (range of 0.4 to 2.5). Mean pump flow during PCI was 2.2 +/- 0.3 L/min. At 30 days, the incidence of major adverse cardiac events was 20% (2 patients had a peri-procedural myocardial infarction; 2 patients died at days 12 and 14). There was no evidence of aortic valve injury, cardiac perforation, or limb ischemia. Two patients (10%) developed mild, transient hemolysis without clinical sequelae. None of the patients developed hemodynamic compromise during PCI. The authors concluded that the Impella 2.5 system is safe, easy to implant, and provides excellent hemodynamic support during high-risk PCI.

Granfeldt et al (2009) reported the use of the Impella device at 3 cardiothoracic units in Sweden. A total of 50 patients (35 men, mean age of 55.8 years, range of 26 to 84) underwent implantation of 26 ImpellaLP 2.5/5.0 (support-time 0.1 to 14 days), 16 ImpellaLD (support-time 1 to 7 days) and 8 ImpellaRD (support-time 0.1 to 8 days) between 2003 and 2007. Implantation was performed because of post-cardiotomy heart failure (surgical group, n = 33) or for various states of heart failure in cardiological patients (non-surgical group, n = 17). The intention for the treatments was mainly to use the pump as a "bridge-to-recovery". Early mortality in the surgical and non-surgical groups was 45% and 23%, respectively. Complications included infection, 36% and right ventricular failure, 28%. Cardiac output and cardiac power output post-operatively were significantly higher among survivors than non-survivors. The authors concluded that the Impella
recovery axial-flow system facilitates treatment in acute heart failure. Early intervention in patients with acute heart failure and optimized hemodynamics in the post-implantation period seem to be of importance for long-term survival. Insufficient early response to therapy should urge to consider further treatment options.

Seyfarth and co-workers (2008) examined if the Impella LP 2.5 provides superior hemodynamic support compared with the intra-aortic balloon pump (IABP) for patients with cardiogenic shock (n = 26). The primary end point was the change of the cardiac index (CI) from baseline to 30 mins after implantation. Secondary end points included lactic acidosis, hemolysis, and mortality after 30 days. In 25 patients, the allocated device (n = 13 for IABP, n = 12 for Impella LP 2.5) could be safely placed. One patient died before implantation. The CI after 30 mins of support was significantly increased in patients with the Impella LP 2.5 compared with patients with IABP (Impella: DeltaCI = 0.49 +/- 0.46 L/min/m²; IABP: DeltaCI = 0.11 +/- 0.31 L/min/m²; p = 0.02). Overall 30-day mortality was 46% in both groups. The authors concluded that in patients presenting with cardiogenic shock caused by acute myocardial infarction, the use of the Impella LP 2.5 is feasible and safe, and provides superior hemodynamic support compared with standard treatment using an IABP.

In a review on circulatory assistance in acute heart failure, Hermansen and colleagues (2009) stated that the findings regarding the use of the Impella axial-flow recovery system for circulatory assistance in patients with acute heart failure, especially for those with cardiogenic shock not related to cardiac surgery, calls for cautious optimism. Additionally, in a systematic review on the prevention and treatment of cardiogenic shock (O'Connor and Fraser, 2009), percutaneous LVADs are not listed as an option.

Furthermore, in a meta-analysis, Cheng et al (2009) evaluated potential benefits of percutaneous LVAD on hemodynamics and 30-day survival for the treatment of cardiogenic shock. Two
independent investigators searched Medline, Embase, and Cochrane Central Register of Controlled Trials for all controlled trials using percutaneous LVAD in patients with cardiogenic shock, where after data were extracted using standardized forms. Weighted mean differences (MDs) were calculated for CI, mean arterial pressure (MAP), and pulmonary capillary wedge pressure (PCWP). Relative risks (RRs) were calculated for 30-day mortality, leg ischemia, bleeding, and sepsis. In main analysis, trials were combined using inverse-variance random effects approach. Two trials evaluated the TandemHeart and a recent trial used the Impella device. After device implantation, percutaneous LVAD patients had higher CI (MD 0.35 \text{L/min/m}^2, 95\%\ CI: 0.09 to 0.61), higher MAP (MD 12.8 mmHg, 95\%\ CI: 3.6 to 22.0), and lower PCWP (MD -5.3 mm Hg, 95\%\ CI: -9.4 to -1.2) compared with patients who received IABP. Similar 30-day mortality (RR 1.06, 95\%\ CI: 0.68 to 1.66) was observed using percutaneous LVAD compared with IABP. No significant difference was observed in incidence of leg ischemia (RR 2.59, 95\%\ CI: 0.75 to 8.97) in percutaneous LVAD patients compared with IABP patients. Bleeding (RR 2.35, 95\%\ CI: 1.40 to 3.93) was significantly more observed in TandemHeart patients compared with patients treated with IABP. The authors concluded that although percutaneous LVAD provides superior hemodynamic support in patients with cardiogenic shock compared with IABP, the use of these more powerful devices did not improve early survival. These results do not yet support percutaneous LVAD as first-choice approach in the mechanical management of cardiogenic shock.

A systematic review of the evidence for percutaneous LVADs from McGill University Health Center (Esfandiari et al, 2009) found "reported experience of this device is still limited." The systematic review found that, of 45 publications, 21 are small case series, and 24 are single case reports. The review explained that, in general the device is being used in 2 ways, for prophylactic use and rescue use. The report found that the Impella has been used “prophylactically” to provide vascular support during elective procedures such as percutaneous coronary interventions in dangerously compromised patients.
for a total of 143 cases. All of these patients were successfully weaned from the device and the estimated survival rate was 0.951 (95% CI: 0.89 to 1.00). The report found that the Impella has been used as a "rescue" intervention in 131 cases of otherwise uncorrectable acute vascular collapse. Of these the rate of successful weaning from the pump was 0.82 (95% CI: 0.70 to 0.94), and the survival rate 0.71 (95% CI: 0.52 to 0.89). The report noted that significant complications were rare, and that hemolysis, when reported, was mild. Reporting on their own experience at McGill Health Center, they found that the Impella device to be more clinically effective than intraaortic balloon pump or extracorporeal membrane oxygenation. They also found the Impella to be less traumatic and less expensive than other available ventricular assist devices.

The American College of Cardiology (Levine et al., 2011) reviewed the evidence for the Impella pVAD for high-risk percutaneous coronary intervention (PCI). They noted that the Impella has been used in patients with cardiogenic shock as well as elective PCI. The ACC guideline (Levine et al., 2011) noted that the hemodynamic effects of the Impella have been studied in high-risk PCI patients, demonstrating beneficial left ventricular unloading effect (decreased end-diastolic pressure and wall stress) with no change in global or systolic left ventricular function. The guideline stated that the PROTECT I (A Prospective Feasibility Trial Investigating the Use of the IMPELLA Recover LP 2.5 System in Patients Undergoing High-Risk PCI) trial in 20 patients undergoing high-risk PCI with the Impella 2.5 system concluded that this device was safe, easy to implant, and hemodynamically effective (citing Dixon et al, 2009). The guideline also cited the Europella registry, which included 144 patients undergoing high-risk PCI and reported the safety, feasibility, and potential usefulness of the device and that randomized controlled trials were warranted (citing Sjauw et al, 2009). The guideline stated, however, that the randomized PROTECT II (A Prospective, Multicenter, Randomized Controlled Trial of the IMPELLA Recover LP 2.5 System Versus Intra Aortic Balloon Pump in Patients Undergoing Non Emergent High Risk PCI) trial, which was designed to
demonstrate superiority of Impella over intra-aortic balloon pump in terms of 1-month adverse events, was halted for futility after interim analysis of study results.

The Levitronix CentriMag Right Ventricular Assist System (RVAS) is intended to provide temporary circulatory support (up to 14 days) for individuals in cardiogenic shock due to acute right ventricular failure. John et al (2007) reviewed their experience with the use of the CentriMag circulatory support system in patients with refractory acute cardiogenic shock and multi-system organ failure whose neurologic status was uncertain. From January 2004 to June 2006, 30 patients underwent CentriMag circulatory support system placement at the University of Minnesota. Of these patients, 12 were transferred from an outside hospital with refractory acute cardiogenic shock requiring biventricular support; they are the focus of this study. Of the 12 study patients, 8 underwent successful bridging to the HeartMate XVE (Thoratec Corp, Pleasanton, CA) VAD after biventricular support (mean support time of 9.4 days, range of 5 to 22 days). Another 2 patients underwent successful explantation (after 8 and 9 days); the remaining 2 patients died (after 4 days). Thus, the survival on CentriMag support, to either bridge or recovery, was 83% (10/12). Of the 8 patients who subsequently underwent HeartMate implantation, 5 also underwent a heart transplant within 6.9 months (range of 4.5 to 10 months), another 2 are still awaiting a transplant, and 1 died of sepsis and right ventricular failure 3 days after HeartMate implantation. Thus, for the 12 study patients, long-term survival was 75% at 1 month and 62.5% at 1 year. The authors concluded that their aggressive strategy in this group of patients involved early operative intervention and implantation of biventricular support. By using this strategy, they avoided the urgent placement of expensive long-term VADs in hemodynamically unstable patients with multi-system organ failure whose neurologic status was uncertain until end-organ recovery and excellent hemodynamic stability were achieved with the relatively inexpensive short-term CentriMag circulatory support system. The excellent mid-term outcomes in this group of patients whose original
prognosis was poor justify this therapeutic strategy.

Shuhaiber and colleagues (2008) reported their clinical experience with the CentriMag device for uni- and bi-ventricular support. Between July 2004 and December 2006, 27 patients were supported using the CentriMag device; 19 were male. Mean age was 47.9 (range of 19 to 72) years. Indications for support at implantation were cardiogenic shock that included: end-stage heart failure and too ill to undergo transplantation, with questionable neurologic status (n = 9); right ventricular failure after left VAD (LVAD) implantation (n = 5); post-cardiotomy status (n = 7); and acute donor graft failure after heart transplantation (n = 6). Post-VAD 30-day survival was 30 % (n = 8). Mean support time was 11 days for all patients (range of 1 to 51 days). Mean support time for 14 Levitronix biventricular VADs was 11 (range of 1 to 51) days. Mean support time for 7 Levitronix LVADs was 13.7 (range of 1 to 30) days. The highest survival rates after Levitronix support were after donor graft failure (50 %) and after cardiotomy (42 %). Levitronix right VAD (RVAD) support after long-term LVAD insertion incurred 100 % hospital mortality. Of those who survived, 8 patients were discharged home after VAD support and remain alive to date. Two patients were bridged to primary and another bridged to repeat heart transplantation. Five patients were weaned to recovery. Re-operation for bleeding occurred in 8 patients, clinical evidence of cerebral thromboembolism in 3, overwhelming sepsis in 1, and aortic thrombus formation in 1. Clot formation in the tubing was observed in 1 patient, necessitating emergent replacement at bedside, which was successful. The authors concluded that the Levitronix CentriMag system is a reliable and facile temporary circulatory support system as a bridge to decision in patients with refractory acute cardiogenic shock.

De Robertis et al (2008) reported their experience with the Levitronix CentriMag short-term VAD as a potential bridge prior to deciding whether a more expensive device should be used or whether transplantation should be undertaken. Since August 2003, 16 moribund patients (14 males; age of 32.7 +/- 14.9;
range of 16 to 62 years) have been supported with the CentriMag device as a "bridge to decision". Twelve patients had an intra-aortic balloon pump pre-operatively, 13 had multi-organ failure, 11 had septic shock, and in 5 patients the neurologic status was uncertain at the time of insertion of the device. Operative mortality was 18.7 % (3 patients); 7 patients (43.7 %) were re-operated for bleeding. The mean support duration was 46.9 +/- 32.3 (range of 6 to 111) days. There were 2 late deaths during Levitronix utilization. Follow-up was 12.8 +/- 12.5 months (range of 0.6 to 43). Eleven patients (68.7 %) are currently alive and well: 2 patients recovered and had the Levitronix device explanted; 6 patients were upgraded to a long-term device; and 3 patients were bridged directly to transplantation. The actuarial survival at 1, 6 and 12 months was 85.7 %, 64.9 % and 64.9 %, respectively. There were no instances of device failure. The authors concluded that the Levitronix device is effective in rescuing critically ill "moribund" patients and can provide an opportunity for low-cost support and optimization of their condition prior to deciding whether a more expensive device should be placed or if transplantation should be undertaken. Better candidate selection for further procedures can then be allowed.

On October 7, 2008, the FDA, via humanitarian device exemption, approved the CentriMag Right Ventricular Assist System (Levitronix LLC, Waltham, MA) to provide temporary circulatory support. The CentriMag is intended to provide temporary circulatory support for up to 14 days for patients in cardiogenic shock due to acute right ventricular failure. It is an extra-corporeal, continuous flow, centrifugal rotary pump intended for temporary use. The device can be used for right or left ventricular assist or in a biventricular configuration.

The Impella RP system is a right percutaneous device that is also designed to provide temporary circulatory support (up to 14 days). It is intended for use in adult or pediatric individuals with a body surface area greater than or equal to 1.5m2 who develop right heart failure or decompensation following LVAD implantation, myocardial infarction (MI), heart transplant or
open heart surgery.

The Excor Pediatric VAD is a miniaturized pneumatic pump system designed to provide mid- to long-term mechanical circulatory support for infants and children with severe heart failure (ECRI, 2013). According to the manufacturer, the Excor pediatric device is the first VAD designed specifically for use in infants, children, and adolescents. In December 2011, FDA granted Berlin Heart marketing approval for the Excor Pediatric VAD under Humanitarian Device Exemption (HDE) status for use in pediatric patients with severe isolated left ventricular or biventricular dysfunction who are candidates for cardiac transplant and require circulatory support.

In an IDE trial, Fraser et al (2012) reported that survival rates were significantly higher with the Excor ventricular assist device than with ECMO as a bridge to transplantation in children with severe heart failure. The investigators conducted a prospective, single-group trial of the Excor pediatric VAD as a bridge to heart transplantation. Patients 16 years of age or younger were divided into 2 cohorts according to body-surface area (cohort 1, less than 0.7 m\(^2\); cohort 2, 0.7 to less than 1.5 m\(^2\)), with 24 patients in each group. Survival in the 2 cohorts receiving mechanical support (with data censored at the time of transplantation or weaning from the device owing to recovery) was compared with survival in 2 propensity-score-matched historical control groups (1 for each cohort) undergoing extracorporeal membrane oxygenation (ECMO). For participants in cohort 1, the median survival time had not been reached at 174 days, whereas in the matched ECMO group, the median survival was 13 days (\(p < 0.001\) by the log-rank test). For participants in cohort 2 and the matched ECMO group, the median survival was 144 days and 10 days, respectively (\(p < 1.1\) by the log-rank test). Serious adverse events in cohort 1 and cohort 2 included major bleeding (in 42 % and 50 % of patients, respectively), infection (in 63 % and 50 %), and stroke (in 29 % and 29 %).

As a condition of approval, the FDA required the company to
conduct a post-approval study to evaluate whether safety and outcomes of Excor use in general clinical practice are comparable to the safety and outcomes reported in the IDE trial (ECRI, 2013).

In a multi-center, double-blind, sham-procedure controlled trial, Ascheim and colleagues (2014) examined whether allogeneic mesenchymal precursor cells (MPCs) injected during LVAD implantation may contribute to myocardial recovery. A total of 30 patients were randomized (2:1) to intra-myocardial injection of 25 million MPCs or medium during LVAD implantation. The primary safety end-point was incidence of infectious myocarditis, myocardial rupture, neoplasm, hypersensitivity reaction, and immune sensitization (90 days after randomization). Key effectiveness end-points were functional status and ventricular function while temporarily weaned from LVAD support (90 days after randomization). Patients were followed-up until transplant or 12 months after randomization, whichever came first. Mean age was 57.4 (± 13.6) years, mean LVEF was 18.1 %, and 66.7 % were destination therapy LVADs. No safety events were observed. Successful temporary LVAD weaning was achieved in 50 % of MPC and 20 % of control patients at 90 days (p = 0.24); the posterior probability that MPCs increased the likelihood of successful weaning was 93 %. At 90 days, 3 deaths (30 %) occurred in control patients, and none occurred in MPC patients. Mean LVEF after successful wean was 24.0 % (MPC = 10) and 22.5 % (control = 2; p = 0.56). At 12 months, 30 % of MPC patients and 40 % of control patients were successfully temporarily weaned from LVAD support (p = 0.69), and 6 deaths (30 %) occurred in MPC patients. Donor-specific HLA sensitization developed in 2 MPC and 3 control patients and resolved by 12 months. The authors concluded that in this preliminary trial, administration of MPCs appeared to be safe, and there was a potential signal of effectiveness. Moreover, they stated that future studies will evaluate the potential for higher or additional doses to enhance the ability to wean LVAD recipients off support.

Stempien-Otero et al (2015) stated that clinical trials report
improvements in function and perfusion with direct injection of bone marrow cells into the hearts of patients with ischemic cardiomyopathy. Pre-clinical data suggested that these cells improve vascular density, which would be expected to decrease fibrosis and inflammation. These researchers tested the hypothesis that bone marrow stem cells (CD34+) will improve histological measurements of vascularity, fibrosis, and inflammation in human subjects undergoing LVAD placement as a bridge to cardiac transplantation. Subjects with ischemic cardiomyopathy who were scheduled for placement of an LVAD as a bridge to transplantation underwent bone marrow aspiration the day before surgery; the bone marrow was processed into cell fractions (bone marrow mononuclear cells, CD34+, and CD34-). At LVAD implantation, all fractions and a saline control were injected epicardially into pre-determined areas and each injection site marked. At the time of transplantation, injected areas were collected. Data were analyzed by paired Student t test comparing the effect of cell fractions injected within each subject. A total of 6 subjects completed the study. There were no statistically significant differences in complications with the procedure versus control subjects. Histological analysis indicated that myocardium injected with CD34+ cells had decreased density of endothelial cells compared to saline-injected myocardium. There were no significant differences in fibrosis or inflammation between groups; however, density of activated fibroblasts was decreased in both CD34+ and CD34- injected areas. The authors concluded that tissue analysis did not support the hypothesis that bone marrow-derived CD34+ cells promote increased vascular tissue in humans with ischemic cardiomyopathy via direct injection.

Implantable Aortic Counter-Pulsation Ventricular Assist System (e.g., the NuPulseCV iVAS and the Symphony Heart Assist System):

The NuPulseCV iVAS

Jeevanandam et al (2002) stated that the Kantrowitz CardioVAD
(KCV) is an electrically powered, pneumatically driven circulatory assist device that provides diastolic augmentation and systolic unloading to the failing heart. It consists of a 60 cc-pumping chamber, a percutaneous access device (PAD), and an external controller. The pumping chamber, is surgically implanted in the descending thoracic aorta with the patient on cardiopulmonary bypass. Its physiologic function is analogous to that of the intra-aortic balloon pump (IABP). Between 1997 and 2000, a total of 5 men (aged 59 to 73 years) with end-stage cardiomyopathy refractory to maximal drug treatment and with documented hemodynamic improvement on an IABP were enrolled in a feasibility study. Mean bypass time was 157 minutes (range of 120 to 196); mean cross-clamp time was 101 minutes (range of 69 to 144). Patient 1 died intra-operatively. Compared with pre-operative values, at 1 month, cardiac index increased (1.7 to 2.6 L/min/m²) and there were significant decreases in creatinine (2.6 to 1.5 mg/dL), pulmonary capillary wedge pressure (PCWP) (32 to 14 mm Hg), and right atrial pressure (RAP) (19 to 9 mm Hg). NYHA class improved (IV to II). The mean increase in cardiac index with the KCV OFF to ON was 0.53 L/min/m² (36 %); 2 patients were discharged home. The device was used intermittently without thromboembolic complications. The only device related complications were attributed to PAD design and have been corrected. The authors concluded that the initial human trial demonstrated successful implantation of the KCV in end-stage patients, the ability of the device to be used intermittently without anti-coagulation, and documented hemodynamic and functional improvement in the status of these patients. This initial trial was designed to test feasibility in surgical implantation and to test the concept of chronic diastolic augmentation. The number of patients enrolled was small, and although there were trends in many parameters, statistical significance was not obtained. The authors stated that longer-term follow-up would be reported later as the data are obtained; this was a non-randomized single-arm trial and would be followed with a pivotal trial comparing the device to medical management.

Russo and co-workers (2012) stated that IABPs are traditionally
inserted through the femoral artery, limiting the patient's mobility. These investigators used alternate approaches of IABP insertion to provide temporary and minimally invasive support for patients with decompensating, end-stage heart failure (HF). They described the outcomes with closed-chest, transthoracic IABPs by way of the subclavian artery. During a 3-year period, a total of 20 patients underwent subclavian artery-IABP (SC-IABP) in the setting of end-stage HF. The balloon was inserted through a polytetrafluoroethylene graft sutured to the right subclavian artery in 19 patients (95 %) and to the left subclavian artery in 1 patient (5 %). The goal of support was to bridge-to-transplantation in 17 patients (85 %) and bridge-to-recovery in 3 patients (15 %). The primary outcome measure was death during SC-IABP support. The secondary outcomes included survival to the intended end-point of bridge-to-transplantation/bridge-to-recovery, complications during SC-IABP support (e.g., stroke, limb ischemia, brachial plexus injury, dissection, bleeding requiring re-operation, and device-related infection), emergent surgery for worsening HF, and ambulation during IABP support. The duration of balloon support ranged from 3 to 48 days (mean of 17.3 ± 13.1 days). No patients died during SC-IABP support. Of the 20 patients, 14 (70 %) were successfully bridged to transplant or left ventricular-assist device; 2 patients (10 %) required emergent LVAD for worsening HF. The authors concluded that an IABP inserted through the subclavian artery is a simple, minimally invasive approach to mechanical support and is associated with limited morbidity and facilitates ambulation in patients with end-stage HF. They stated that additional studies are needed to evaluate long-term outcomes, the necessity for anti-coagulation, and the cost/benefit ratio of this device compared with alternatives, including LVADs. The major drawbacks of this study were: (i) small sample size (n = 20), (ii) non-randomization of participants, (iii) retrospective case series design, and (iv) limited follow-up.

Estep and colleagues (2013) evaluated the feasibility, tolerability, and effectiveness of a strategy for percutaneous IABP placement through the left axillary-subclavian artery to
provide mechanical circulatory support in patients with end-stage HF as a bridge to heart transplantation. These researchers developed a percutaneous technique for placing IABPs in the left axillary artery that permits upright sitting and ambulation. They performed a retrospective review of data from patients who had undergone left axillary IABP implantation between 2007 and 2012. A total of 50 patients who received a left axillary IABP as a bridge to transplantation were identified, of whom 42 (84%) underwent heart or heart/multi-organ transplantation. Cumulative survival on IABP support was 92%, and post-transplant 90-day survival was 90%. Median duration of support was 18 days; 4 of 50 patients (8%) died while on IABP support, and 3 (6%) received greater mechanical circulatory support; 4 patients (8%) had clinically significant thromboembolic or bleeding events without long-term sequelae. The most common minor AEs was IABP malposition, in 22 patients (44%). Prolonged IABP support in the heart-transplantation cohort was associated with significant improvements in mean pulmonary artery pressure and in creatinine and total bilirubin concentrations. The authors concluded that percutaneous insertion of an IABP through the left axillary artery is a feasible and relatively well-tolerated strategy to bridge patients with end-stage HF to heart transplantation. This form of mechanical-device treatment permits upright sitting and ambulation in those requiring extended support. The major drawbacks of this study were its retrospective nature and it being a single-center study.

Tanaka and associates (2015) noted that a SC-IABP can help to optimize patients with advanced congestive heart failure (CHF) as a bridge to definitive therapy. These investigators retrospectively reviewed their experience to evaluate the application and safety of this technique. They studied 88 patients with decompensated advanced CHF who received SC-IABP placement between January 2011 and December 2014. The SC-IABP was placed through a graft in the subclavian artery. The intended therapeutic goals for SC-IABP were bridge to transplant (n = 61), mechanical circulatory support (n = 21), or recovery (n = 6). Success was defined as stroke-free survival,
achievement of therapeutic goal, and maintenance or improvement in renal function, hemodynamics, and physical conditioning through ambulation and rehabilitation. A total of 80 patients were successfully bridged to the next therapy (transplant 93.4 %, mechanical circulatory support 95.3 %, recovery 50 %). There was no mortality related to SC-IABP placement. Duration of SC-IABP support was 4 to 135 days (median of 21). Failure was attributed to escalation of support (n = 5), stroke (n = 2), and sepsis (n = 1). Mean pulmonary artery pressure significantly improved from 33 ± 11 mm Hg to 28 ± 8 mm Hg (p < 0.05); 84 patients (95.5 %) ambulated more than 3 times a day; 2-minute step test demonstrated significant improvement, from 50 ± 9 steps to 90 ± 23 steps (n = 16, p < 0.001). Specific complications of SC-IABP included exchange/re-positioning (n = 26, 29.5 %), subclavian artery thrombosis (n = 1, 1.1 %), and re-exploration for hematoma (n = 4, 4.5 %) and infection (n = 2, 2.3 %). No distal thromboembolic events were observed. The authors concluded that the SC-IABP provided excellent hemodynamic support with minimal morbidity and mortality, allowed for extensive rehabilitation, and permitted more than 90 % of patients to receive their intended therapy. Therefore, SC-IABP is a compelling bridge device for patients with advanced CHF. The drawbacks of this study were its retrospective, single-center, and non-randomized design. The authors stated that additional follow-up is needed for further validation of their current protocol.

The NuPulseCV iVAS is designed to be a minimally invasive, ambulatory, long-term counter-pulsation system for patients suffering from advanced CHF. Compared to continuous flow LVADs, the iVAS has the potential to expand therapy to less sick patients due to its expected safer complication profile. The device does not need access to the heart via thoracotomy or sternotomy making it forward compatible as a bridge to transplant, recovery or extending medical therapy. There is a clinical trial on the use of the NuPulseCV iVAS for the treatment of bridge-to-transplant patients (a first-in-human (FIH) study). However, this trial has been identified as being associated with a clinical device that has not been approved or cleared by the
The Symphony Heart Assist System

Cecere and colleagues (2015) stated that current cardiac assist devices provide full support, require a major operation, and function asynchronously to the native heart. In contrast, these researchers developed a novel circulatory support device that provides synchronous partial support and can be placed with a minor operation. They reported the first clinical implantation with the Symphony device. Patients with advanced HF despite optimal therapy who had exhausted all options were evaluated. A 64-year old man with ischemic cardiomyopathy underwent implantation of the Symphony device in the right infraclavicular fossa. After initiating device support, the cardiac index increased from 1.7 to 2.5 L/min/m², pulmonary capillary wedge pressure decreased from 26 to 13 mm Hg, right atrial pressure decreased from 12 to 7 mm Hg, creatinine level decreased from 2.3 to 1.5 mg/dL, and NYHA class improved from IIIB to II. The authors concluded that placement of the Symphony device resulted in improvements in hemodynamics and functional status. They stated that further clinical data will help define the role for this approach of partial synchronous support through a less invasive operation in patients with advanced HF; results of this and further clinical studies will help define the potential for these devices to promote recovery of the native heart, and the durability of native heart recovery.

Furthermore, an UpToDate review on “Short-term mechanical circulatory assist devices” (Aroesty et al, 2016) stated that “The intraaortic balloon pump (IABP) is the most commonly used mechanical support device and it is the device interventional cardiologists are most familiar with. It is inserted easily and rapidly, is the least expensive of all the devices, and does not require continuous monitoring by technical support personnel.

https://clinicaltrials.gov/ct2/show/NCT02645539

However, it is limited in that it is capable of generating only modest hemodynamic support and myocardial protection. In addition, clinical trials of patients with cardiogenic shock have not shown an improvement in mortality with its use”.

Appendix

**Table: New York Heart Association (NYHA) Functional Classification of Heart Failure**

<table>
<thead>
<tr>
<th>NYHA Class</th>
<th>Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>No symptoms and no limitation in ordinary physical activity, e.g., shortness of breath when walking, climbing stairs etc.</td>
</tr>
<tr>
<td>II</td>
<td>Mild symptoms (mild shortness of breath and/or angina) and slight limitation during ordinary activity.</td>
</tr>
<tr>
<td>III</td>
<td>Marked limitation in activity due to symptoms, even during less-than-ordinary activity, e.g., walking short distances (20 to 100 m). Comfortable only at rest.</td>
</tr>
<tr>
<td>IV</td>
<td>Severe limitations. Experiences symptoms even while at rest. Mostly bedbound patients.</td>
</tr>
</tbody>
</table>


**CPT Codes / HCPCS Codes / ICD-10 Codes**

*Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":*

**CPT codes covered if selection criteria are met:**

<table>
<thead>
<tr>
<th>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; extracorporeal, single ventricle</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
</tr>
<tr>
<td>--------</td>
<td>------------------------------------------------------------------------------------------------</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 ventricular</td>
</tr>
<tr>
<td>33981</td>
<td>Replacement of extracorporeal ventricular assist device, single or biventricular, pump(s), single or each pump</td>
</tr>
<tr>
<td>33982</td>
<td>Replacement of ventricular assist device pump(s); implantable intracorporeal, single ventricle, without cardiopulmonary bypass</td>
</tr>
<tr>
<td>33983</td>
<td>with cardiopulmonary bypass</td>
</tr>
<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>92970</td>
<td>Cardioassist-method of circulatory assist; internal</td>
</tr>
<tr>
<td>92971</td>
<td></td>
</tr>
<tr>
<td>93750</td>
<td>Interrogation of ventricular assist device (VAD), in person, with physician analysis of device parameters (eg, drivelines, alarms, power surges), review of device function (eg, flow &amp; volume status, recovery), with programming, if performed, &amp; report</td>
</tr>
</tbody>
</table>

**CPT codes not covered for indications listed in the CPB:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>38205-6</td>
<td>Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; allogeneic or autologous [mesenchymal precursor cells]</td>
</tr>
</tbody>
</table>
### Other CPT codes related to the CPB:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>33967</td>
<td>Insertion of intra-aortic balloon assist device, percutaneous</td>
</tr>
<tr>
<td>33970</td>
<td>Insertion of intra-aortic balloon assist device through the femoral artery, open approach</td>
</tr>
<tr>
<td>33973</td>
<td>Insertion of intra-aortic balloon assist device through the ascending aorta</td>
</tr>
<tr>
<td>92920 - 92921</td>
<td>Percutaneous transluminal coronary angioplasty</td>
</tr>
<tr>
<td>92924 - 92925</td>
<td>Percutaneous transluminal coronary atherectomy</td>
</tr>
<tr>
<td>92928 - 92929</td>
<td>Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed</td>
</tr>
<tr>
<td>92933 - 92934</td>
<td>Percutaneous transluminal coronary atherectomy, with intracoronary stent, with coronary angioplasty when performed</td>
</tr>
<tr>
<td>92937 - 92938</td>
<td>Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of intracoronary stent, atherectomy and angioplasty, including distal protection when performed</td>
</tr>
<tr>
<td>92941</td>
<td>Percutaneous transluminal revascularization of acute total/subtotal occlusion during acute myocardial infarction, coronary artery or coronary artery bypass graft, any combination of intracoronary stent, atherectomy and angioplasty, including aspiration thrombectomy when performed</td>
</tr>
<tr>
<td>92943 - 92944</td>
<td>Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of intracoronary stent, atherectomy and angioplasty</td>
</tr>
</tbody>
</table>

**HCPCS codes covered if selection criteria are met:**
<table>
<thead>
<tr>
<th>Q0478</th>
<th>Power adapter for use with electric or electric/pneumatic ventricular assist device, vehicle type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q0479</td>
<td>Power module for use with electric or electric/pneumatic ventricular assist device, replacement only</td>
</tr>
<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>Code</td>
<td>Description</td>
</tr>
<tr>
<td>--------</td>
<td>---------------------------------------------------------------------------------------------------------------------</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/pneumatic ventricular assist device, replacement only</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, other than lithium-ion, for use with electric or electric/pneumatic ventricular assist device, replacement only</td>
</tr>
<tr>
<td>Q0497</td>
<td>Battery clip 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/bag for use to carry external peripheral components of any type ventricular assist device, replacement</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>
</tbody>
</table>
Q0506 Battery, lithium-ion, for use with electric or electric/pneumatic ventricular assist device, replacement only

Q0507 Miscellaneous supply or accessory for use with an external ventricular assist device

Q0508 Miscellaneous supply or accessory for use with an implanted ventricular assist device

Q0509 Miscellaneous supply or accessory for use with any implanted ventricular assist device for which payment was not made under Medicare Part A

**Other HCPCS codes related to the CPB:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>S9348</td>
<td>Home infusion therapy, sympathomimetic/inotropic agent infusion therapy (e.g., Dobutamine); administrative services, professional pharmacy services, care coordination, all necessary supplies and equipment (drugs and nursing visits coded separately), per diem</td>
</tr>
</tbody>
</table>

**ICD-10 codes covered if selection criteria are met:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I23.0 - I23.9</td>
<td>Certain current complications following ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction (within the 28 day period)</td>
</tr>
<tr>
<td>I50.1 - I50.9</td>
<td>Heart failure</td>
</tr>
<tr>
<td>I97.0</td>
<td>Postcardiotomy syndrome</td>
</tr>
<tr>
<td>I97.110</td>
<td>Postprocedural cardiac insufficiency following cardiac surgery</td>
</tr>
<tr>
<td>I97.120</td>
<td>Postprocedural cardiac arrest following cardiac surgery</td>
</tr>
<tr>
<td>I97.130</td>
<td>Postprocedural heart failure following cardiac surgery</td>
</tr>
<tr>
<td>I97.190</td>
<td>Other postprocedural cardiac functional disturbances following cardiac surgery</td>
</tr>
<tr>
<td>R57.0</td>
<td>Cardiogenic shock</td>
</tr>
<tr>
<td>T82.897</td>
<td>Other specified complication of cardiac prosthetic devices, implants and grafts</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
</tr>
<tr>
<td>----------</td>
<td>--------------------------------------------------</td>
</tr>
<tr>
<td>T86.298</td>
<td>Other complications of heart transplant</td>
</tr>
<tr>
<td>Z76.82</td>
<td>Awaiting organ transplant status [awaiting heart transplant]</td>
</tr>
<tr>
<td>Z95.811</td>
<td>Presence of heart assist device</td>
</tr>
</tbody>
</table>

The above policy is based on the following references:


22. Mundy L, Merlin T. Thoratec heartmate (R) left ventricular assist device for patients with heart failure who are ineligible for heart transplantation. Horizon Scanning Prioritising Summary - Volume 2. Adelaide, SA: Adelaide Health Technology Assessment (AHTA) on behalf of National Horizon Scanning Unit (HealthPACT and MSAC); 2003.


cost-effectiveness of left ventricular assist devices as
destination therapy for people with end-stage heart
failure: A systematic review and economic evaluation. Int
31. Miller LW, Pagani FD, Russell SD, et al; HeartMate II
Clinical Investigators. Use of a continuous-flow device in
2007;357(9):885-896.
devices as a bridge to heart transplantation in children. J
multicenter trial of the VentrAssist left ventricular assist
device for bridge to transplant: Safety and efficacy. J
prophylactic percutaneous left ventricular assist device
(TandemHeart) in high-risk percutaneous coronary
intervention using an arterial preclosure technique:
TandemHeart, percutaneous transseptal left ventricular
assist device: A safeguard in high-risk percutaneous
coronary interventions. The six-year Rotterdam
experience with the TandemHeart percutaneous
ventricular assist device to support patients undergoing
high-risk percutaneous coronary intervention. J Invasive
Recover 2.5 left ventricular assist device in patients with
cardiogenic shock or undergoing high-risk percutaneous
coronary intervention procedures: Experience of a
high-volume center. Minerva Cardioangiol.
trial to evaluate the safety and efficacy of a percutaneous


AETNA BETTER HEALTH® OF PENNSYLVANIA

Amendment to
Aetna Clinical Policy Bulletin Number: CPB
0654 Ventricular Assist Devices

There are no Amendments for Medicaid

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Updated 05/2017