DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (i.e., will be paid for by Molina) for a particular member. The member's benefit plan determines coverage. Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this Molina Clinical Policy (MCP) document and provide the directive for all Medicare members.  

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL

Percutaneous ventricular assist devices (pVADs) have been developed for short-term use in patients who require acute circulatory support. These devices are intended for individuals requiring partial circulatory support using an extracorporeal; bypass control unit during procedures not requiring cardiopulmonary bypass. These devices are placed through the femoral artery. Two different pVADs have been developed, the TandemHeart™ (Cardiac Assist™, Pittsburgh, PA), and the Impella® device (AbioMed™, Aachen, Germany). In the TandemHeart™ system, a catheter is introduced through the femoral artery and passed into the left atrium via transseptal puncture. Oxygenated blood is then pumped from the left atrium into the arterial system via the femoral artery. The Impella device is also introduced through a femoral artery catheter. In this device, a small pump is contained within the catheter that is placed into the left ventricle. Blood is pumped from the left ventricle, through the device, and into the ascending aorta. Adverse events associated with pVAD include access site complications such as bleeding, aneurysms, or leg ischemia. Cardiovascular complications can also occur, such as perforation, myocardial infarction (MI), stroke, and arrhythmias.

The Impella® Recover LP 2.5 Percutaneous Cardiac Support System received FDA 510(k) approval in May 2008 for partial circulatory support using an extracorporeal bypass control unit for periods up to 6 hours. It is also intended to be used to provide partial circulatory support (for periods up to 6 hours) during procedures not requiring cardiopulmonary bypass.  The TandemHeart® (Cardiac Assist, Pittsburgh) received initial 510(k)
approval for the CardiacAssist TandemHeart pump and controller in 2000 and initial approval for the cannula set in 2003. Subsequent approvals were issued for an updated cannula set and an updated controller in 2006. The TandemHeart is intended to be used for partial circulatory support using an extracorporeal bypass control unit for periods up to 6 hours. It is also intended to be used to provide partial circulatory support (for periods up to 6 hours) during procedures not requiring cardiopulmonary bypass. The Impella 5.0 Catheter Family received 510(k) substantial equivalence clearance on April 16, 2009. The IMPELLA 5.0 Catheters are intended for circulatory support using an extracorporeal bypass control unit, for periods up to 6 hours. They are also intended to be used to provide circulatory support (for periods up to 6 hours) during procedures not requiring cardiopulmonary bypass.

### INITIAL COVERAGE CRITERIA

The Percutaneous Ventricular Assist Devices (pVAD) may be authorized when all of the following criteria are met: [ALL]

- The pVAD must be an FDA approved device (e.g., TandemHeart® System, Impella Recover® LP 2.5 Percutaneous Cardiac Support System, and Impella Recover® LP 5.0 Percutaneous Cardiac Support System); and

- For partial circulatory support short term use (up to 6 hours) for any of the following clinical indications: [ONE]
  - ST segment elevation myocardial infarction (STEMI) when unable to be stabilized with pharmacological therapy
  - Refractory cardiogenic shock
  - As an adjunct to PCI in carefully selected high-risk patients: [ONE]
    - undergoing unprotected left main or last-remaining patent conduit PCI;
    - severely depressed ejection fraction (≤ 35%) undergoing PCI of a vessel supplying a large territory;
    - three vessel disease with ejection fraction ≤ 30%;
    - presence of cardiogenic shock

### CONTINUATION OF THERAPY

The Percutaneous Ventricular Assist Devices (pVAD) may only be used short term (for up to 6 hours).

### COVERAGE EXCLUSIONS

The Percutaneous Ventricular Assist Device (pVAD) is contraindicated when any of the following conditions are present:

- Ventricular Septal Defect (VSD)
- Right Ventricular Failure
- Known hemoglobin diseases such as sickle cell or thalassemia
- Mural thrombus in LV (Impella)
- Peripheral arterial disease (TandemHeart)

**SUMMARY OF MEDICAL EVIDENCE**

6-34

**Cardiogenic Shock**

Kar and colleagues (2011) sought to evaluate the efficacy and safety of the percutaneous ventricular assist device (pVAD) in patients in severe refractory cardiogenic shock (SRCS) despite intra-aortic balloon pump (IABP) and/or high-dose vasopressor support. A total of 117 patients with SRCS implanted with TandemHeart pVAD (CardiacAssist, Inc., Pittsburgh, Pennsylvania) were studied, of whom 56 patients (47.9%) underwent active cardiopulmonary resuscitation immediately before or at the time of implantation. Data was collected regarding clinical characteristics, hemodynamics, and laboratory values. Eighty patients had ischemic and 37 patients had nonischemic cardiomyopathy. The average duration of support was 5.8 ± 4.75 days. After implantation, the cardiac index improved from median 0.52 (interquartile range [IQR]: 0.8) L/(min•m(2)) to 3.0 (IQR:0.9) L/(min•m(2)) (p < 0.001). The systolic blood pressure and mixed venous oxygen saturation increased from 75 (IQR:15) mm Hg to 100 (IQR:15) mm Hg (p < 0.001) and 49 (IQR:11.5) to 69.3 (IQR:10) (p < 0.001), respectively. The urine output increased from 70.7 (IQR: 70) ml/day to 1,200 (IQR: 1,620) ml/day (p < 0.001). The pulmonary capillary wedge pressure, lactic acid level, and creatinine level decreased, respectively, from 31.53 ± 10.2 mm Hg to 17.29 ± 10.82 mm Hg (p < 0.001), 24.5 (IQR: 74.2 5) mg/dl to 11 (IQR: 92) mg/dl (p < 0.001), and 1.5 (IQR: 95) mg/dl to 1.2 (IQR: 9) mg/dl (p = 0.009). The mortality rates at 30 days and 6 months were 40.2% and 45.3%, respectively. The authors concluded that the pVAD rapidly reversed the terminal hemodynamic compromise seen in patients with SRCS refractory to IABP and vasopressor support.

Cheng and colleagues (2009) performed a meta-analysis of controlled trials to evaluate potential benefits of percutaneous LVAD on haemodynamics and 30-day survival. 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 cardiac index (CI), mean arterial pressure (MAP), and pulmonary capillary wedge pressure (PCWP). Relative risks (RRs) were calculated for 30-day mortality, leg ischaemia, 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 L/min/m(2), 95% CI 0.09-0.61), higher MAP (MD 12.8 mmHg, 95% CI 3.6-22.0), and lower PCWP (MD -5.3 mm Hg, 95% CI -9.4 to -1.2) compared with IABP patients. Similar 30-day mortality (RR 1.06, 95% CI 0.68-1.66) was observed using percutaneous LVAD compared with IABP. No significant difference was observed in incidence of leg ischaemia (RR 2.59, 95% CI 0.75-8.97) in percutaneous LVAD patients compared with IABP patients. Bleeding (RR 2.35, 95% CI 1.40-3.93) was significantly more observed in TandemHeart patients compared with patients treated with IABP. The authors concluded that although percutaneous LVAD provides superior haemodynamic 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. 18

Seyfarth et al. (2008) performed a controlled study of the Impella Recover LP 2.5. This study was a randomized controlled trial that evaluated the Impella Recover LP 2.5 for treatment of cardiogenic shock rather than as a support during high-risk PCI. A total of 26 patients who had cardiogenic shock due to acute MI were enrolled (19 men, 7 women; median age 66 years; mean cardiac output 3.3 L/min; mean cardiac index 1.7 L/min/m2) and they were assigned to equal-sized treatment groups that underwent cardiac assistance with an Impella device for a median of 25 hours (range 6-41) or an IABP device for a median of 23 hours (range 14-34). There were no statistically significant differences between the Impella and IABP Groups at baseline. Although 1 (8%) Impella Group patient died before device implantation, this patient was retained in the study since results were analyzed on an intent-to-treat basis. Shortly after implantation, a statistically significant improvement was seen in diastolic arterial pressure for the Impella Group (74 ± 17 mm Hg) versus the IABP Group (50 ± 16 mm Hg) (P=0.002); however, due to hemolysis, the Impella device was associated with statistically significant increases in free hemoglobin at 1, 6, 12, and 24 hours, which exceeded 40 mg/dL at peak (P<0.05). At 30 minutes after implantation, mean cardiac index had increased 0.5 ± 0.5 L/min/m2 for the Impella Group versus 0.1 ± 0.3 L/min/m2 for the IABP Group. Although this difference was statistically significant (P=0.02), by 4 hours, the difference in mean cardiac index had disappeared. Likewise, the Impella Group had a statistically significant increase in cardiac power index at 30 minutes but not at 2, 4, 6, 14, or 22 hours. In addition, there were no significant differences between the Impella and IABP Groups in mean cardiac output, arterial pressure, systolic arterial pressure, pulmonary capillary wedge pressure, right atrial pressure, systemic vascular resistance, serum lactate concentrations, multiple organ dysfunction scores, or sepsis-related organ failure scores. Mortality after 30 days was 46% for both the Impella and IABP Groups. 6

The prospective, randomized multicenter study by Burkhoff and colleagues (2006) compared the safety and efficacy of the TandemHeart System with that of IABP in patients with cardiogenic shock (CS). The aim of this prospective randomized study was to test the hypothesis that the TandemHeart (pVAD) provides superior hemodynamic support compared with intraaortic balloon pumping (IABP). Forty-two patients from 12 centers presenting within 24 hours of developing CGS were included in the study and treated in an initial roll-in phase (n = 9) or randomized to treatment with IABP (n = 14) or TandemHeart pVAD (n = 19). Thirty patients (71%) had persistent CGS despite having an IABP in place at the time of study enrollment. Cardiogenic shock was due to myocardial infarction in 70% of the patients and decompensated heart failure in most of the remaining patients. The mean duration of support was 2.5 days. Compared with IABP, the TandemHeart pVAD achieved significantly greater increases in cardiac index and mean arterial blood pressure and significantly greater decreases in pulmonary capillary wedge pressure. Overall 30-day survival and severe adverse events were not significantly different between the 2 groups. In conclusion, in patients presenting within 24 hours of the development of CGS, TandemHeart significantly improves hemodynamic parameters, even in patients failing IABP. Larger-scale studies are required to assess the influence of improved hemodynamics on survival. 13

Burkhoff et al (2006) completed another study to investigate the feasibility, safety, and hemodynamic impact of the TandemHeart percutaneous left ventricular assist device (pVAD) in CGS. Thirteen patients from five
centers in the US with the diagnosis of CGS were enrolled in the study. Hemodynamic measurements, including cardiac index (CI), mean arterial pressure (MAP), pulmonary capillary wedge pressure (PCWP), and central venous pressure (CVP) were performed presupport, during support and after device removal. Patients were monitored for 6 months. The pVAD was successfully implanted in all 13 patients, with duration of support averaging 60 +/- 44 hr. During support, CI increased from 2.09 +/- 0.64 at baseline to 2.53 +/- 0.65 (P = 0.02), MAP increased from 70.6 +/- 11.1 to 81.7 +/- 14.6 (P = 0.01), PCWP decreased from 27.2 +/- 12.2 to 16.5 +/- 4.8 (P = 0.01), and CVP from 12.9 +/- 3.7 to 12.6 +/- 3.6 (P = NS). Ten patients survived to device explant, 6 of who were bridged to another therapy. Seven patients survived to hospital discharge and were all alive at 6 months. The two most common adverse events were distal leg ischemia (n = 3) and bleeding from the cannulation site (n = 4). In summary, the TandemHeart PTVA System may be a useful complementary treatment for patients with CGS, especially as a bridge to another treatment. Further study is needed to definitively establish safety and efficacy.

**Complex Cardiovascular Procedures**

Tempelhof et al (2011) presented the clinical outcomes and safety associated with the use of TandemHeart among a series of heterogeneous patients requiring PVAD support. They reviewed the clinical experience, hemodynamic variables, survival outcomes, and complications associated with the implantation of TandemHeart support device among 25 patients presenting at one institution. Indications for PVAD implantation were cardiogenic shock (56%), ST-segment elevation myocardial infarction (STEMI) (20%), postpericardiotomy (16%), and high-risk percutaneous coronary interventions (PCI) or ventricular tachycardia (VT) ablation (8%). TandemHeart was used for an average of 4.8 ± 2.1 days and demonstrated significant hemodynamic improvements (pre- and postimplantation left ventricular ejection fractions were 21.5% ± 15% and 24.5% ± 10.5%, respectively [p = 0.06]). The cardiac index improved from a mean 2.04 ± 075 L/min/m² to 2.45 ± 073 L/min/m² (p = 0.09). The mixed venous oxygen saturation (SVO2) increased from 55.14 ± 13.34 to 66.43 ± 7.43 (p = 0.008) after implantation. TandemHeart was used as a bridge to left ventricular assist device implantation (44%) or recovery (20%). Thirty-six percent of patients died on support or shortly after PVAD removal. Thirty, 90-day, and long-term (>90 days) survival rates were 56%, 52%, and 36%, respectively. Procedure-related complications were reported in 13 patients (56%), and the majority (90%) was related to vascular access (bleeding or pseudoaneurysm). The authors concluded the TandemHeart device is a safe therapeutic option as a bridge-to-recovery or bridge-to-bridge for patients with hemodynamic compromise regardless of the etiology. The favorable hemodynamic profile, postimplantation survival rates, and manageable complications support its use to assist hemodynamic recovery in patient’s refractory to conventional therapy.

Thomas et al (2010) sought to describe the use of the TandemHeart percutaneous left ventricular assist device (PVAD) in a group of high-risk patients undergoing complex cardiovascular procedures. Thirty-seven high-risk patients underwent placement of the TandemHeart PVAD during 38 separate procedures between April 2007 and April 2009. PVAD insertion was considered emergent if a patient was not expected to survive more than 6 hours without PVAD support. Technical success was defined as successful initiation of the PVAD and completion of the intended interventional procedure. All 37 patients were in cardiogenic shock or undergoing
complex coronary and valvular interventions with a high probability of hemodynamic collapse. The mean (+/- standard deviation) patient age was 73 +/- 14 years; 97% were in either NYHA class III-IV heart failure or cardiogenic shock; and the mean EuroSCORE was 11 +/- 3.4. Indications for ventricular assist device placement included critical aortic stenosis (n = 8), severe left main coronary stenosis (n = 18), severe multivessel coronary stenosis (n = 19) and severe cardiomyopathy (n = 23). Four patients were being managed for fulminant myocarditis, ventricular free-wall rupture, flail mitral valve or severe paravalvular leak. Despite their critical status and frequent (82%) need for post-procedure blood transfusion, this complex and high-risk patient population tolerated PVAD-supported intervention well and technical success was achieved in all patients. Seventy-one percent of patients survived to hospital discharge with improved functional status. Most deaths occurred in patients not expected to survive due to their moribund status and multiorgan failure. Investigators concluded this experience demonstrated the utility and effectiveness of TandemHeart PVAD support in patients with advanced disease, critical clinical status and limited therapeutic options.

Percutaneous coronary intervention (PCI)

O’Neill and colleagues (2012) published the results of the PROTECT II study. This was a randomized clinical trial hemodynamic support with Impella 2.5 versus intra-aortic balloon pump in patients undergoing high-risk percutaneous coronary intervention. 452 symptomatic patients with complex 3-vessel disease or unprotected left main coronary artery disease and severely depressed left ventricular function were randomly assigned to intra-aortic balloon pump (IABP) (n=226) or Impella 2.5 (n=226) support during nonemergent high-risk percutaneous coronary intervention. The primary end point was the 30-day incidence of major adverse events. A 90-day follow-up was required, as well, by protocol. Impella 2.5 provided superior hemodynamic support in comparison with IABP, with maximal decrease in cardiac power output from baseline of -0.04±0.24 W in comparison with -0.14±0.27 W for IABP (P=0.001). The primary end point (30-day major adverse events) was not statistically different between groups: 35.1% for Impella 2.5 versus 40.1% for IABP, P=0.227 in the intent-to-treat population and 34.3% versus 42.2%, P=0.092 in the per protocol population. At 90 days, a strong trend toward decreased major adverse events was observed in Impella 2.5-supported patients in comparison with IABP: 40.6% versus 49.3%, P=0.066 in the intent-to-treat population and 40.0% versus 51.0%, P=0.023 in the per protocol population, respectively. The authors concluded that the 30-day incidence of major adverse events was not different for patients with IABP or Impella 2.5 hemodynamic support. However, trends for improved outcomes were observed for Impella 2.5-supported patients at 90 days.

Kovacic et al. (2015) evaluated the efficacy of Impella 2.5 compared with IABP in a subgroup of 325 patients with 3-vessel CAD and LVEF ≤ 30% in an analysis of the PROTECT II study. Results of this preplanned subgroup analysis of the PROTECT II study suggests that use of Impella 2.5 compared with IABP seems to reduce the composite incidence of MAE at 90 days, but not at 30 days.

Shah et al (2012) investigated seventy-four consecutive patients undergoing high-risk PCI and those with cardiogenic shock (CS) receiving intraaortic balloon pump (IABP), TandemHeart (TH), or Impella device (IMP) were enrolled. Patient undergoing high-risk PCI (n=57) and those treated for CS (n=17) were analyzed as
separate cohorts. Patients undergoing IABP-assisted PCI were compared to those undergoing PLVAD (TH and IMP)-assisted PCI. The primary end point was in-hospital major adverse cardiovascular events, and the secondary end point was in-hospital vascular complications. For the high-risk PCI cohort (n=57), 22 received PLVAD and 35 received IABP. Patients receiving IABP were younger and less likely to have a prior myocardial infarction (MI) and less likely to be on dialysis compared to those receiving PLVAD support. Patients receiving PLVAD support had a higher baseline Syntax score, had a higher prevalence of unprotected left main disease, underwent treatment of more coronary lesions, received more coronary stents, and more likely received drug-eluting stents compared to those receiving IABP support. The primary and secondary end points were similar between both groups. For the CS cohort (n=17), 4 received PLVAD and 13 received IABP. Patients receiving PLVAD support were more likely to have a prior MI, had a lower ejection fraction, underwent treatment of more coronary lesions, and received more coronary stents compared to those receiving IABP support. The primary and secondary end points were similar between both groups. Investigators concluded IABP compared with PLVAD use for high-risk PCI and CS is associated with significantly different baseline patient, clinical, procedural, and angiographic characteristics. In-hospital clinical outcome was similar between both groups in both the high-risk PCI and the CS cohorts. When physicians have access to each of these devices, short-term clinical outcome appears to be similar.  

Maini and colleagues (2012) reported on a multicenter experience of the Impella 2.5 circulatory support system during high-risk PCI, a subset of the larger USpella Registry. 175 consecutive patients who underwent high-risk PCI with prophylactic support of the Impella 2.5 were evaluated. The primary safety endpoint was the incidence of major adverse cardiac events (MACE) at 30 days. Secondary endpoints included safety and efficacy related to the device and patient outcomes, including survival at 12 months. Overall angiographic revascularization was successful in 99% of patients and in 90% of those with multivessel revascularization, resulting in a reduction of the mean SYNTAX score post-PCI from 36 ± 15 to 18 ± 15 (P < 0.0001) and an improvement of the ejection fraction (from 31 ± 15% to 36 ± 14%, P < 0.0001). In 51% of patients, the functional status improved by one or more NYHA class (P < 0.001). At 30-day follow-up, the rate of MACE was 8%, and survival was 96%, 91%, and 88% at 30 days, 6 months, and 12 months, respectively. The use of Impella 2.5 in high-risk PCI appeared feasible and safe in the real-world setting. The utilization of the Impella 2.5 was successful, resulting in favorable short- and midterm angiographic, procedural and clinical outcomes. 

Alli and colleagues (2012) performed a retrospective cross-sectional analysis of prospectively collected data in 54 patients undergoing high-risk PCI using the TandemHeart device for support. Hemodynamic and clinical data were collected and analyzed. Baseline clinical characteristics were: mean age 72 ± 1.7 years, males 78%, median ejection fraction 20%, mean serum creatinine 1.6 ± 0.3 2 mg/dL, recent myocardial infarction 52%, COPD 33%, previous CABG 50%, diabetes mellitus 41%, and hypertension 83%. The median SYNTAX score was 33, and the median Jeopardy score was 10. The predicted surgical revascularization mortality was 13% by the Society for Thoracic Surgery risk score and 33% by Euroscore. There was a significant decrease in right and left heart pressures (P < 0.05) with a concomitant increase in the cardiac output from 4.7 to 5.7 L/min (P = 0.03) during TandemHeart support. Left main and multivessel PCI was performed in 62% of patients, and rotablation was used in 48%. Procedural success rate was 97%, whereas 30-day and 6 month survival were 90% and 87%, respectively. Major vascular complications occurred in 13% of cases. None of our patients developed contrast
induced nephropathy or needed dialysis. The authors concluded that high-risk PCI with percutaneous left ventricular support using TandemHeart is a viable therapeutic strategy for a select subset of patients at very high risk with standard percutaneous revascularization techniques. 19

Kovacic et al (2011) compared the practical use, safety and clinical outcomes associated with the TandemHeart (TH) versus Impella Recover 2.5 (IR2.5) devices when used for circulatory support during high-risk percutaneous coronary intervention (PCI), noting these P-LVADs differ markedly in their insertion, operation and manner of circulatory augmentation. Investigators identified 68 patients (49 males, 19 females; age 71.1±12.1 years) from a single-center database that underwent 'high-risk' PCI with P-LVAD support from 04/2005-06/2010 (32 with TH, 36 with IR2.5). Relevant data were extracted and imputed for analysis. Baseline demographics were similar, including low LVEF (overall mean 31.0±13.7%) and elevated STS mortality risk score (4.2±3.7%). Angiographic characteristics were also similar, with a mean of 2.4±1.0 lesions treated per patient, and 29% undergoing left main PCI. PCI success rates were 99% in both groups, with similar in-hospital outcomes and a combined 7% major vascular access site complication rate. A single episode of left atrial perforation occurred during TH use. No patient required emergent CABG and no in-hospital deaths occurred. The 30 day MACE rate (death, myocardial infarction, target lesion revascularization) was 5.8%. There were no differences between the IR2.5 and TH groups with respect to short- or long-term clinical outcomes. Investigators concluded the IR2.5 and TH assist devices are safe, equally effective, and associated with acceptable short- and long-term clinical outcomes in patients undergoing 'high-risk' PCI. 16

Schwartz and colleagues (2011) performed a retrospective study to determine the baseline characteristics, hemodynamics, and outcomes of patients treated with prophylactic percutaneous left ventricular assist devices (PLVADs) during HR-PCI. Fifty cases were identified (5 IABP, 13 Impella, 32 TandemHeart). Mean ejection fraction was 31 ± 17%. All devices (100%) were initiated successfully. Angiographic success was achieved in 96% (80% IABP, 100% Impella, 97% TandemHeart). Of the 38 patients not in cardiogenic shock, death occurred in 1 (2.6%), recurrent ischemia in 3 (8%), and stroke in 0%. Shortly after device removal, systolic blood pressure (mean increase, +5 ± 22 mmHg) and ejection fraction (mean increase, +7.4 ± 11%; p = 0.0006) increased in all 3 groups, suggesting a beneficial effect on the myocardium. In patients undergoing HR-PCI with Impella and TandemHeart support, angiographic success was high and major complication rates were low. The authors concluded that a tiered approach where patients with the least, intermediate, and highest risk of left ventricular failure are treated with an IABP, Impella, or Tandem-Heart, respectively, theoretically maximizes appropriate hemodynamic support and minimizes complications. 27

Dixon et al. (2009) conducted an uncontrolled study of the Impella Recover LP 2.5 and it enrolled 20 patients (17 men, 3 women; mean age 60 years; mean left ventricular ejection fraction [LVEF] 26%) who underwent cardiac support during high-risk PCI. The mean duration of pump use was 1.7 hours (range 0.4-2.5) and during this time, a mean of 2.4 lesions were treated. Pump implantation and operation was successful in all patients and all patients had successful PCI procedures. During the procedures, 2 (10%) patients had MI without clinical
sequelae and 2 (10%) other patients died on days 12 and 14 after treatment. Neither death was attributed to use of the Impella device and no patients developed ventricular fibrillation or ventricular tachycardia during or within a week after pump use. In addition, echocardiography in 16 (80%) of the patients indicated that no aortic or mitral valve damage occurred during pump use. 7

Vranckx and colleagues (2009) retrospectively evaluated the short-term safety and efficacy of the TandemHeart percutaneous transseptal left ventricular assist (PTVA) system to deliver extracorporeal circulatory support during catheter based treatment of the unprotected left main coronary artery (ULMCA). Between July 2002 and May 2008 the TandemHeart was used in 9 very high risk patients (Logistic Euro score: 13.64 (7.46-29.67); Syntax score:43 (41-50); Mayo Clinic Risk score (MCRS) 7 (6-8); age: median 65 (range 55-71) undergoing elective PCI for the novo lesions on the ULMCA. All patients were declined for CABG by a heart team. A "true" percutaneous insertion technique was used in all patients, technical success rate was 100%. The median (range) time for implementation of circulatory support was 27 min (24-30). A median (range) pump flow up to 4.36 (3.40-5.54) L/min was achieved with significant reduction of left ventricular filling pressures, pulmonary capillary wedge pressure and a small increase of systemic arterial pressures. Median (range) duration of support was 93 min (50.4-102). Successful weaning was achieved in all patients. There was no in hospital death, survival at 6 months was (89%), whereas vascular access site complications were seen in 4 patients (44.4%). The authors concluded that in very high risk PCI, assisted circulation using the TandemHeart-PTVA provides effective, total left ventricular support and may contribute to a reduced procedural risk and improved survival. The rate of device related cardiac and vascular complications was acceptable. 22

In another small case series, Vranckx and colleagues (2008) published the results of 23 patients undergoing PCI who were supported with the TandemHeart between September 2000 to July 2006. The TandemHeart, supported the circulation of 23 patients (age: range 46-74, mean 59) admitted to our center 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 minutes (range 16-62). The index PCI was successful in all patients except two. A pump flow up to 4L/min was achieved with significant reduction of left ventricular filling pressures, pulmonary capillary wedge pressure and with significant increase of systemic arterial pressures. Duration of support ranged from 1-222 hours (mean 31+/-.49.8 hours). Five patients died with the TandemHeart in place, four 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 <36.5 degrees C in six patients, profound hypothermia (Ct <35 degrees C) was observed in two patients. There was no technical device failure. The authors concluded that the TandemHeart - PTVA provides effective, total left ventricular support in very high risk PCI settings. The rate of device related cardiac and vascular complications was acceptable. 21

Another small uncontrolled study of the Impella Recover LP 2.5 was conducted by Burzotta et al. (2008). This study enrolled 10 male patients (mean age 64 ± 9 years, mean LVEF 31% ± 8%) who underwent high-risk PCI.
Impella device implantation was successful and no complications arose except in 1 (10%) patient who died a few hours after PCI due to acute stent thrombosis. The other 9 (90%) patients were all discharged ≤ 5 days after treatment. At 10 months follow-up, LVEF had increased from 31% ± 7% to 41% ± 13% (P=0.02) and during the 12 months following treatment, 2 (20%) patients required a second PCI. 10

Remmelink et al. (2007) conducted a smaller study that may partially or completely overlap with the 2006 study by Henriques et al. described below. The study enrolled 11 patients (7 men, 4 women; mean age 67 ± 9 years; mean LVEF 35% ± 11%) who underwent high-risk PCI. During use of the Impella device, statistically significant 6% to 48% improvements were observed in mean aortic pressure, distal coronary pressure, peak flow velocity, coronary flow velocity reserve, and coronary microvascular resistance. However, this study did not report outcomes of the PCI procedures. 9

An earlier uncontrolled study of the Impella Recover LP 2.5 for cardiac support was performed by Henriques et al. (2006) and it enrolled 19 patients, most of whom underwent high-risk PCI. All patients were elderly with 16 (84%) aged > 60 years (mean age was not reported), 14 (74%) had prior MI, 12 (63%) had LVEF ≤ 25%, and all had LVEF ≤ 40%. In 17 (89%) patients, the Impella device was used during elective PCI and in the other 2 (11%) patients, it was used for urgent PCI or as a last resort cardiac support. Implantation of the Impella device was successful in all patients; however, the latter 2 patients died 1 day after the procedure. Echocardiography or angiography in 12 (63%) patients indicated that there were no appreciable changes in aortic valve regurgitation after treatment and no other significant device-related adverse events occurred. 8

Valgimigli et al. (2006) performed an uncontrolled study16 that evaluated use of the Impella Recover LP 2.5 during high-risk PCI in 10 patients (mean age 62 ± 10 years, mean LVEF 37% ± 16%). The Impella device was used for a mean of 144 ± 88 minutes. Before and at several time points up to 48 hours after device use, the following biomarkers were measured: free Hemoglobin (fHb), B-type natriuretic peptide, catecholamines, aldosterone, angiotensin II, and endothelin. No substantial changes were observed in these biomarkers except for fHb, which temporarily increased 2-fold to 14-fold above the normal upper limit in 4 (40%) patients. Although this observation suggests that the Impella device causes variable levels of hemolysis, the results did not report whether the increase in fHb was statistically significant compared with baseline. A substantial change was also seen in left ventricular volume loading, which increased acutely in 6 (60%) patients after device insertion and tended to remain elevated even at the highest pump speed. Volume loading appeared to neutralize the blood pumping action of the Impella Recover LP 2.5; however, these findings were reported in pressure-volume graphs without quantitatively measuring the magnitude of the effect. 11

Professional Organizations 37-41

The 2015 Society for Cardiovascular Angiography and Interventions / American College of Cardiology / Heart Failure Society of America / Society for Thoracic Surgeons (SCAI/ACC/HFSA/STS) consensus statement on the use of percutaneous mechanical circulatory support (MCS) states that percutaneous MCS, particularly with the Impella and TandemHeart, is superior to pharmacologic therapy for providing hemodynamic support and these devices should be available and reimbursed (Rihal et al., 2015). One of the suggested indications for
Percutaneous MCS is for patients undergoing high-risk PCI, especially if the patient is inoperable or has a low LVEF (< 20% to 30%) and complex CAD involving a large territory (i.e., sole remaining vessel, left main disease, or 3-vessel disease). \(^{39}\)

ACCF/AHA/SCAI guideline for percutaneous coronary artery intervention. A report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Society for Cardiovascular Angiography and Interventions indicates that elective insertion of an appropriate percutaneous hemodynamic support device as an adjunct to PCI may be reasonable in carefully selected high-risk patients. \(^{37}\)

**Coding Information:** The codes listed in this policy are for reference purposes only. Listing of a service or device code in this policy does not imply that the service described by this code is covered or non-covered. Coverage is determined by the benefit document. This list of codes may not be all inclusive.

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<tr>
<th>CPT</th>
<th>Description</th>
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<tbody>
<tr>
<td>33990</td>
<td>Insertion of ventricular assist device, percutaneous including radiological supervision and interpretation; arterial access only</td>
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<tr>
<td>33991</td>
<td>Insertion of ventricular assist device, percutaneous including radiological supervision and interpretation; both arterial and venous access, with transseptal puncture</td>
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<tr>
<td>33992</td>
<td>Removal of percutaneous ventricular assist device at separate and distinct session from insertion</td>
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<th>HCPCS</th>
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**ICD-9**

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<tr>
<td>37.68</td>
<td>Insertion of percutaneous external heart assist device</td>
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<tr>
<td>410.00-411.89</td>
<td>Acute myocardial infarction and other acute and subacute forms of ischemic heart disease</td>
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<tr>
<td>414.00-414.07</td>
<td>Coronary atherosclerosis</td>
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<tr>
<td>428.0-428.9</td>
<td>Heart failure</td>
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<td>785.51</td>
<td>Cardiogenic shock</td>
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**ICD-10**

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<tr>
<td>I20-I25.9</td>
<td>Ischemic Heart Disease</td>
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<td>I50-I50.9</td>
<td>Heart Failure</td>
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<tr>
<td>R57.0</td>
<td>Cardiogenic shock</td>
</tr>
</tbody>
</table>

**Resource References**

**Government Agency**


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Peer Reviewed Publications


**Professional Society Guidelines**


**Other Resources**

42. Hayes Health Technology Brief. Winifred Hayes Inc. Lansdale, PA.

- Impella 2.5 System (Abiomed Inc.) for Cardiac Support in Patients Undergoing High-Risk Percutaneous Coronary Intervention (PCI). July 2015
- Impella 5.0 (Abiomed Inc.) for Emergent Hemodynamic Support in Patients with Cardiogenic Shock. Sept. 2015
- Impella 2.5 System (Abiomed Inc.) for Emergent Hemodynamic Support in Patients with Cardiogenic Shock. Sept. 2015
- Impella 2.5 System (Abiomed Inc.) for Cardiac Support in Patients Undergoing High-Risk Percutaneous Coronary Intervention (PCI). June, 2016

43. UpToDate: Aroesty JM, Jeevanandam V, Eisen HJ. Short-term mechanical circulatory assist devices. 2016.