Molina Clinical Policy
Percutaneous Ventricular Assist Devices: Policy No. 132

Last Approval: 12/14/2022
Next Review Due By: December 2023

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment and clinical recommendations for the Member. 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 (e.g., 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 MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Percutaneous ventricular assist devices (pVADs) have been developed for short-term use in patients who require acute circulatory support. Most of the components of the device are external to the body and are for short-term use (6 hours to 14 days) only. Given the external nature they carry an increased risk of infection and need for careful, in-hospital monitoring. These devices are intended for individuals requiring partial circulatory support using an extracorporeal bypass control unit during procedures that do not require cardiopulmonary bypass. pVADs are a treatment option in patients who are failing conventional therapy, (such as traditional VAD or intra-aortic balloon pump (IABP) for short-term), for partial or total hemodynamic support, or those in which conventional therapy cannot be used, but who require acute circulatory support. pVADs differ from other types of VADs as these devices are 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. This review does not address other forms of circulatory support such as IABP, extracorporeal membrane oxygenation, or all combined procedures which are unique to the inpatient setting.

Adverse events (AEs) 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 devices are placed through the femoral artery or vein. Two pVADs have been developed, the TandemHeart™ (Cardiac Assist), and the Impella® device (Abiomed):

- In the TandemHeart system, a catheter is introduced through the femoral vein and passed into the left atrium via transseptal puncture. Oxygenated blood is then pumped from the left atrium into the arterial system via the femoral artery. Complications may include cannula migration, tamponade due to perforation, thromboembolism, air embolism during cannula insertion, and inter-atrial shunt development.
- The Impella device is introduced through a femoral artery catheter. In this device, a small pump is contained within the catheter that is placed into the left ventricle. Blood is pumped from the left ventricle, through the device, and into the ascending aorta. Most Impella devices can be placed percutaneously through the femoral artery (or the femoral vein for Impella RP), but the Impella 5.0 typically requires an arterial cut-down procedure, and the Impella LD is placed during open chest procedures (Ait Ichou, 2017). AEs associated with pVAD include access site complications such as bleeding, aneurysms, or leg ischemia. Cardiovascular complications can also occur, such as perforation, MI, stroke, and arrhythmias.

Regulatory Status

The Impella 2.5 device received FDA 510(k) clearance (K063723) on May 30, 2008, for partial circulatory support for ≤ 6 hours, 21 CFR 870.4360 Nonroller-type blood pump. The approval of the Impella RP heart pump follows the FDA humanitarian device exemption (HDE), which Abiomed received in January 2015 and adds the Impella RP heart pump to Abiomed's platform of approved devices, including the Impella 2.5, Impella CP, Impella 5.0, and Impella LD heart pumps. Other devices, including the Impella CP, have since also received clearance or approval with an expanded indication for cardiogenic shock on April 7, 2016 (P140003 S004). The duration of the Impella heart pumps for cardiogenic shock was expanded to up to 14 days on May 06, 2019 (P140003 S049). Multiple additional PMA supplemental approvals have been issued for the Impella devices including labeling changes, post-approval study protocols, and manufacturing process changes.

The TandemHeart (Cardiac Assist; now TandemLife) received a 510(k) approval (K052570) for short-term circulatory support in January 2006, product code DWF (Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass). Subsequent device approval was recieved K110493 in 2011, product code KFM (Pump, Blood, Cardiopulmonary Bypass, Non-Roller Type). The system (manufactured by CardiacAssist Inc.; now TandemLife) consists of a pump, a cannula set, and a controller.

FDA Approved Indications

High-Risk Percutaneous Coronary Intervention (PCI). The Impella 2.5, Impella CP and Impella CP with SmartAssist Systems are temporary (≤ 6 hours) ventricular support devices indicated for use during high-risk PCI performed in elective or urgent, hemodynamically stable patients with severe coronary artery disease, when a heart team, including a cardiac surgeon, has determined high-risk PCI is the appropriate therapeutic option.

Cardiogenic Shock. The Impella 2.5, Impella CP, Impella CP with SmartAssist, Impella 5.0, Impella 5.5 with SmartAssist and Impella LD Catheters (in conjunction with the Automated Impella Controller; collectively, "Impella System Therapy"), are temporary ventricular support devices intended for short-term use (≤ 4 days for the Impella 2.5, Impella CP, and the Impella CP with SmartAssist, and ≤ 14 days for the Impella 5.0, Impella 5.5 with SmartAssist and Impella LD) and indicated for the treatment of ongoing cardiogenic shock that occurs immediately (< 48 hours) following acute MI or open heart surgery or in the setting of cardiomyopathy, including peripartum cardiomyopathy, or myocarditis as a result of isolated LV failure that is not responsive to optimal medical management and conventional treatment measures (including volume loading and use of pressors and inotropes, with or without intra-aortic balloon pumps (IABP).

Right Heart Failure. The Impella RP System is indicated for providing temporary right ventricular support for up to 14 days in patients with a body surface area ≥1.5 m^2, who develop acute right heart failure or decompensation following left ventricular assist device (LVAD) implantation, MI, heart transplant, or open-heart surgery.

COVERAGE POLICY

pVAD may be considered medically necessary when **ALL** of the following criteria are met:

1. The requested pVAD is an FDA-approved device and intended use is in accordance with FDA-labeled indications; **AND**
2. For partial circulatory support short-term use as indicated (up to 14 days); **AND**
3. Member meets **ONE** of the following clinical indications and prescribed according to the labeling of pVAD:
    a. As an adjunct to PCI in the following *high-risk patients undergoing invasive cardiac or *electrophysiological procedures who need circulatory support:
        - Undergoing unprotected left main or last-remaining patent conduit vessel with ejection fraction less than 35%; **OR**
        - Severely depressed ejection fraction (≤ 35%) undergoing PCI of a vessel supplying a large territory; **OR**
        - Triple vessel disease with end diastolic ejection fraction less than 30%.
          *Triple vessel disease defined as at least one significant stenosis (e.g., 75% or greater stenosis by diameter) in all three major epicardial territories

*Note:
- *Electrophysiological procedures who need circulatory support is defined as a procedure that is sometimes used with ventricular fibrillation or ventricular tachycardia electrophysiology study/ablations in the setting of left ventricular dysfunction.
- *The definition of high-risk PCI is evolving, however consensus is forming that this group of patients 'involves a confluence of characteristics, including complex coronary artery disease (multivessel or left main disease and anatomically complex coronary lesions), hemodynamic compromise (shock or severely depressed LV function), and clinical comorbidities such as advanced age, diabetes mellitus, peripheral vascular disease, heart failure, acute coronary syndromes, or previous cardiac surgery (Bass et al. 2015)'.

b. STEMI when unable to be stabilized with pharmacological ionotropic therapy; **OR**

c. Cardiogenic shock (defined as persistent hypotension with systolic blood pressure less than 90 mmHg or mean arterial pressure 30 mmHg below baseline, cardiac index less than 1.8 L/min/m² without support or less than 2.2 L/min/m² with support, or adequate or elevated filling pressures to 5 by left ventricular end-diastolic pressure greater than 18 mmHg or right ventricular end-diastolic pressure greater than 10 mmHg)*, as an alternative to IABP; or cardiogenic shock refractory to medications (vasopressors and inotropes) with/without IABP

d. For the Impella RP System and Impella 5.5 with SmartAssist only:
Member has a body surface area (BSA) ≥ 1.5 m^2 with acute right heart failure or decompensation as a result of any of the following circumstances:
    - Following left ventricular assist device (LVAD) implantation; OR
    - Cardiogenic shock due to acute MI, heart transplant, or open-heart surgery that is not responsive to optimal medical management and conventional treatment measures.

CONTINUATION OF THERAPY
Continuation of therapy is not applicable. pVAD may only be used short-term (for up to 14 days) with initial authorization only.

LIMITATIONS AND EXCLUSIONS
pVAD is **contraindicated and may not be authorized** if **ANY** of the following circumstances are present:
- Mechanical aortic valve or heart constrictive device;
- Aortic valve stenosis/calcification (graded as ≥ +2 (equivalent to an orifice area of 1.5 cm^2 or less);
- Moderate to severe aortic insufficiency (echocardiographic assessment of aortic insufficiency graded as ≥ +2).

Device-specific contraindications (as applicable):

1. The Impella 2.5, Impella CP, Impella CP with SmartAssist, Impella 5.0, Impella 5.5 with SmartAssist and Impella LD are contraindicated for use with patients experiencing ANY of the following conditions:
    a. Mural thrombus in the left ventricle
    b. Presence of a mechanical aortic valve or heart constrictive device
    c. Aortic valve stenosis/calcification (equivalent to an orifice area of 0.6cm^2 or less)
    d. Severe peripheral arterial disease precluding placement of the Impella System

    Conditions contraindicated for the cardiogenic shock indication only:
    a. Significant right heart failure
    b. Combined cardiorespiratory failure
    c. Presence of an Atrial or Ventricular Septal Defect (including post-infarct VSD)
    d. Left ventricular rupture
    e. Cardiac tamponade

OR

2. TandemHeart system is contraindicated for use with patients experiencing ANY of the following conditions:
    a. Ventricular septal defects
    b. Right ventricular failure (may cause right to left shunting and hypoxemia)
    c. Right or left atrial thrombosis
    d. Moderate to severe aortic insufficiency; aortic dissection
    e. Coagulopathies and bleeding disorders
    f. Contraindication to anticoagulation
    g. Severe peripheral arterial disease that may prevent cannula insertion

The following are considered **experimental, investigational, and unproven** based on insufficient evidence:
1. Any indications other than those listed above

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

The published evidence consists of randomized controlled trials (RCTs), clinical trials, meta-analysis, systematic reviews, and retrospective studies that evaluated the efficacy and safety of pVAD for the management of cardiogenic shock, as an adjunct to high- riskPCI, acute heart failure caused by left ventricular dysfunction and/or cardiogenic shock, unstable patients with ST segment elevation MI and in other complex cardiovascular procedures. Most RCTs compared pVAD to IABP. Complications have been reported when using pVADs with high-risk PCI procedures, but several studies have shown that the major AE rate at 30 and 90+ days post pVADs are favorable. Studies of patients with cardiogenic shock refractory to IABP have reported improved hemodynamic parameters following pVAD placement. Most recent evidence from the Premier Healthcare database used propensity-matching to show the rapid increase in use of the Impella device and marked variability in use and adverse outcomes. There were higher odds of death, and wide variation in bleeding and stroke underscoring the need to define appropriate usage and indications (Amin et al. 2020). Additional registry data showed that patients treated with Impella had higher in-hospital mortality compared to balloon pump.

High-Risk PCI

O'Neill et al. (2012) conducted this prospective multicenter randomized trial (PROTECT II) to assess whether a high-risk PCI strategy with the support of the Impella 2.5 device would result in better outcomes than a revascularization strategy with IABP support (n=452). Improved outcomes were observed for Impella 2.5-supported patients at 90-day follow-up. Patients were age 18 or older and scheduled to undergo a non-emergent PCI on an unprotected left main or last patent coronary vessel, with a left ventricular ejection fraction (LVEF) of ≤ 35%, or with 3-vessel disease and LVEF ≤ 30%. Patients were randomized to IABP (n=226) or Impella 2.5 (n=226) during nonemergent PCI. The primary endpoint was the composite rate of intra- and post-procedural major AEs at discharge or 30-day follow-up, whichever was longer. Between November 27, 2007 and December 6, 2010, 452 patients were enrolled; 69% of the planned enrollment. After review of the available interim data, the Data and Safety Monitoring Board (DSMB) recommended the early discontinuation of the study for futility based on the observed conditional power of the 30-day results of the first 327 patients and the assumed similar trend for the remaining patients to be included in the study. (When enrollment ceased, an additional 125 patients had been enrolled beyond the initial 327 patients). Based on an intent-to-treat analysis, there was no statistically significant difference in the primary endpoint, major AE at 30 days, between patients in the Impella arm (35.1%) and the IABP arm (40.1%) (p=0.277). A follow-up of the composite primary end point was also performed at 90 days and showed a trend toward decreased major AE in the Impella arm (40.6%) compared to the IABP arm (49.3%) (p=0.066) in the intent-to-treat population, and 40.0% vs. 51.0% (p=0.023), in the per-protocol population, respectively. The authors acknowledged that because the difference in 30-day major AE did not reach statistical significance for the entire study, the analysis of 90-day events remains exploratory.

The 2015 SCAI/ACC/HFSA/STS Clinical Expert Consensus Statement on the Use of Percutaneous Mechanical Circulatory Support Devices in Cardiovascular Care cited the PROTECT II trial as 'is the largest single randomized clinical trial of high-risk PCI using MCS ever performed and enrolled 452 symptomatic patients with complex three-vessel disease or unprotected left main coronary artery disease and severely depressed LV function to IABP (n = 226) or Impella 2.5 (n = 226) support for high-risk PCI.' The 2015 consensus statement also notes, 'No comparable randomized trial of HR-PCI with the TandemHeart device exists. The reported a series of 54 patients (Alli et al. 2012) using the TandemHeart for HR-PCI and other small series of patients undergoing HR-PCI with TandemHeart support were mentioned (have also been reported (Thomas et al. 2010; Bagai et al. 2011).

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

High-Risk PCI Systematic Review and Meta-Analysis

Rios et al. (2018), in a meta-analysis, compared the benefits and harms of IABP versus pVAD (TandemHeart and the Impella 2.5, CP or 5.0) during high-risk PCI or cardiogenic shock. Five RCTs were included (Thiele et al., 2005 [n=20]; Burkhoff et al. 2006 [n=35]; Seyfarth et al. 2008 [n=32]; O'Neill et al., 2012 [n=236]; Ouweneel et al., 2017 [n=48]) and one non-randomized study comparing pVAD versus IABP. Based on the RCTs, there was no difference in short-term (6 months) (p=0.59) or long-term (12 months) (p=1.00) all-cause mortality.

Ichou et al. (2018) conducted a systematic review to synthesize the available evidence on the effectiveness and safety of the Impella 2.5 or 5.0 devices in high-risk patients undergoing PCI. The studies consisted of 4 RCTs (Seyfarth et al., 2008; O'Neil et al., 2012; Ouweneel et al. 2016, 2017) and 16 observational studies, including a total of 1287 patients. All studies were published between 2006 and 2016, and the durations of follow-up ranged from 1-42 months. Ten studies examined prophylactic use of the Impella device among high-risk patients undergoing elective PCI, five examined its use among high-risk patients undergoing emergent PCI, and four examined its use in mixed populations of high-risk patients undergoing elective or emergent PCI. Mean LVEF was low, ranging from 23%-37%, while the percentage of patients with previous MI was variable, ranging from 24%-76%. Overall, patients had multiple comorbidities and were at high procedural risk. The use of Impella resulted in improved procedural and hemodynamic characteristics in controlled and uncontrolled studies. In controlled studies, the 30-day rates of all-cause mortality and major adverse cardiac events (MACE) were similar across groups. In most uncontrolled studies, the 30-day rates of all-cause mortality were generally low (range: 3.7%–10%), though rates of MACE were slightly higher (range: 5%–20%). The authors concluded that there is limited evidence available concerning the effect of Impella on clinical events, particularly compared to IABP, although procedural and hemodynamic results appear promising.

Briasoulis et al (2016) conducted a systematic review and meta-analysis that included studies of both Impella and TandemHeart to assess the effects of PVAD use on mortality, MI, and complication rates in patients undergoing high-risk PCI The authors included 18 non-randomized observational studies and a single RCT (PROTECT II). The review included 12 studies with 1,346 participants who underwent Impella 2.5 L device placement and 8 cohort studies with 205 patients that received TandemHeart device for high-risk PCI. The primary outcome measures were 30-day all-cause mortality, 30-day MI rates, periprocedural major bleeding, and vascular complications. Both devices are associated with comparable periprocedural outcomes in patients undergoing high-risk PCI. Short-term mortality rates were 3.5% and 8% and major bleeding rates were 7.1% and 3.6% with Impella and TandemHeart, respectively. Both devices are associated with comparable periprocedural outcomes in patients undergoing high-risk PCI. The pooled vascular complication rates were 4.9% and 6.5% for the Impella and the TandemHeart, respectively. This meta-analysis did not compare pVAD to IABP or other interventions.

Cardiogenic Shock

The evidence includes RCTs, observational studies, and systematic reviews for cardiogenic shock or high-risk cardiac procedures receiving a pVAD. Relevant outcomes are overall survival, symptoms, morbid events, functional outcomes, QOL, and treatment-related mortality and morbidity. Four RCTs of pVAD vs IABP for patients in cardiogenic shock failed to demonstrate a mortality benefit and reported higher complication rates with pVAD use. Comparative observational studies were consistent with the RCT evidence.

- RCTs, controlled and uncontrolled observational studies, and systematic reviews of these studies have not demonstrated a benefit of pVAD used as ancillary support for patients undergoing high-risk cardiac procedures. The evidence is insufficient to determine the effects of the technology on health outcomes.
- For individuals with cardiogenic shock refractory to IABP therapy who receive a pVAD, the evidence includes case series and relevant outcomes are OS, symptoms, morbid events, functional outcomes, QOL, and treatment-related mortality and morbidity. Case series of patients with cardiogenic shock refractory to IABP have reported improved hemodynamic parameters following pVAD placement. However, these uncontrolled series do not provide evidence that pVADs improve mortality, and high rates of complications have been reported with pVAD use. The evidence is insufficient to determine the effects of the technology on health outcomes.

Cardiogenic Shock Randomized Controlled Trials

A total of 4 RCTs have compared pVADs with IABPs for patients who had cardiogenic shock (Thiele et al. 2005; Burkhoff et al. 2006; Seyfarth et al. 2008; Ouweneel et al. 2017). Three RCTs were included in the systematic reviews conducted by Romeo et al. 2016 and Cheng et al. 2009 and one RCT (Ouweneel et al. 2017) was published after the reviews. The 4 RCTs enrolled a total of 148 patients, 77 treated with a pVAD and 71 treated with an IABP. All 4 trial populations included patients with AMI and cardiovascular shock; 1 trial restricted its population to patients who were post revascularization in the AMI setting. The primary outcomes reported were 30-day mortality, hemodynamic measures of left ventricle pump function, and AEs. Improvements in hemodynamic and metabolic parameters, but none found any reductions in 30-day mortality. The IMPRESS trial compared outcomes following Impella or IABP in patients presenting with STEMI and cardiogenic shock and undergoing primary PCI. IMPRESS reported outcomes following mechanical circulatory support are similar with the two groups. Bleeding events and leg ischemia were more common in the pVAD groups.

Study/Trial (Registration)/Dates	Countries/Sites	pVAD	Key Eligibility Criteria
Ouweneel et al. (2017) IMPRESS (NTR3450); 2012- 2015	Netherlands, Norway/2	Impella CP	AMI and severe CS in the setting of immediate PCI; receiving mechanical ventilation
Seyfarth et al. (2008) ISAR-SHOCK (NCT00417378); 2004-2007	Germany/2	Impella LP 2.5	AMI <48 h and CS
Burkhoff et al. (2006) TandemHeart (NR); 2002-2004	U.S./12	TandemHeart	CS <24 h due to MI or heart failure
Thiele et al. (2005) NR; 2000-2003	Germany/1	TandemHeart	AMI with CS and intent to revascularize with PCI

A randomized, prospective, open-label, multicenter study by Ouweneel et al. (2017) was conducted to determine whether a new percutaneous mechanical circulatory support (MCS) device (Impella CP) decreases 30-day mortality when compared with an IABP in patients with severe shock complicating acute MI. A total of 48 patients with severe cardiogenic shock complicating acute MI were assigned to percutaneous MCS (n=24) or IABP (n=24). Severe cardiogenic shock was defined as systolic blood pressure <90 mm Hg or the need for inotropic or vasoactive medication and the requirement for mechanical ventilation. The primary endpoint was 30-day all-cause mortality. At 30 days, mortality in patients treated with either IABP or percutaneous MCS was similar (50% and 46%, respectively). At 6 months, mortality rates for both percutaneous MCS and IABP were 50%.

Cardiogenic Shock Systematic Reviews and Meta-Analysis

Batsides et al. (2018) conducted a systematic review and meta-analysis to investigate the survival outcomes and device-related complications of Impella 5.0 use in patients with cardiogenic shock. The primary outcome was survival to discharge. This meta-analysis included 6 studies (n=163). Five studies were observational retrospective studies, and one was a prospective single arm study. Indications for support included 88 (54.0%) for acute on chronic decompensated heart failure, 35 (21.5%) for post-cardiotomy cardiogenic shock, 27 (16.6%) for acute MI complicated by cardiogenic shock, and 13 (8.0%) for cardiogenic shock due to other reasons. The overall estimated survival to discharge, 30, 180, and 365 days was 73.5%, 72.6%, 62.7%, and 58.4%, respectively. Patients supported for post-cardiotomy cardiogenic shock had the highest heart recovery among survivors to explant (92.1%) and highest survival at 30 (89.5%) and 365 days (69.5%).

A meta-analysis of randomized trials by Thiele et al. (2017) investigated the efficacy and safety of percutaneous active mechanical support system (MCS) vs. control (IABP) in cardiogenic shock. The primary endpoint of 30-day mortality and device-related complications including bleeding and leg ischemia were analyzed. Four trials randomizing 148 patients to either TandemHeart or Impella MCS (n=77) vs. control (n=71) were identified. Two trials used the TandemHeart device (Thiele et al. 2005; Burkhoff et al. 2006) and 2 trials used the Impella device [Impella 2.5 (Seyfarth, et al., 2008) and Impella CP (Ouweneel, et al., 2017)]. There was no difference in 30-day mortality. The authors recommend that the use of active percutaneous MCS may thus be restricted to selected patients.

Romeo et al. (2016) reported on a systematic review and meta-analysis that evaluated various percutaneous mechanical support methods, including pVADs, for patients with cardiogenic shock due to acute MI who were undergoing revascularization. A total of 6 trials and 271 patients (n=271) were included; 3 RCTs comparing pVADs with IABPs (Thiele et al. 2005; Burkhoff et al. 2006; Seyfarth et al. 2008) and 3 comparative observational studies

(Schwartz et al. 2012; Shah et al. 2012; Manzo-Silberman 2013). Of note, this systematic review included the same 3 RCTs as an earlier meta-analysis conducted by Cheng et al. (2009). Romeo et al. noted that the major limitation was the small sample size of the RCTs. In the comparison of pVADs with IABP, reviewers found that in-hospital mortality (the primary outcome of the analysis) was non-significantly increased in the pVAD group. Subgroup analysis did not find significant differences in estimates from RCTs and observational studies, and CIs overlapped. There was no significant heterogeneity within RCTs or observational studies. The relative risk reduction was -17.23%, translating to 8 more deaths per every 100 patients treated with pVADs instead of IABP.

Acute Heart Failure

The RECOVER RIGHT trial (NCT1777607) a prospective, open-label, single arm, non-randomized, multicenter study involving 30 patients with right ventricular failure (RVF) refractory to medical treatment. The primary objective for the study was to assess safety and effectiveness of the use of the Impella RP device in patients with RVF refractory to medical treatment who require hemodynamic support. A total of 30 patients (N=30) enrolled in the trial were divided into two patient cohorts; Cohort A including patients (n=18) who developed RVF within 48 hours after implantation of a left ventricular assist device (LVAD), while Cohort B investigated patients (n=12) who developed RVF within 48 hours of post-cardiotomy shock or post-acute MI shock. Primary endpoints were patient survival at 30 days, hospital discharge, or bridge to subsequent additional therapy. Overall, survival rate among the enrolled subjects was 73% in the entire population at 30 days. Cohort A showed a survival rate of 83.3% and Cohort B showed a 58.3% survival rate at 30 days. The FDA Summary of Safety and Probable Benefit overall conclusions state that the RECOVER RIGHT was the first study of a percutaneous RVAD in patients with RVF refractory to medical treatment who had very limited therapeutic options. In the studied patient population, the use of the Impella RP device provided adequate circulatory support to reverse shock and to restore normal hemodynamic parameters and achieved an overall survival rate of 73% at 30 days or discharge (whichever is longer) or to a long-term therapy. Anderson et al. concluded that mechanical support with the Impella RP device in patients with RVF resulted in rapid hemodynamic improvement with reversal of shock and favorable survival and the preliminary findings for the Impella RP support probable benefit in gravely ill population. The researchers also suggest that the device may represent as a strategy as a bridge therapy to recovery or to a definitive therapy. However, the study is not conclusive with respect to the use of the Impella RP System in individuals with acute right heart failure or decompensation following LVAD implantation, MI, heart transplant, or open-heart surgery.

National and Specialty Organizations

American Association for Thoracic Surgery (AATS)/International Society for Heart and Lung Transplantation
Guidelines published by the AATS and the International Society for Heart and Lung Transplantation (2020) on selected topics in mechanical circulatory support, including recommendations on the use of pVADs, noted that 'Compared with IABP, contemporary percutaneous circulatory support devices provide a significant increase in cardiac index and mean arterial pressure; however, reported 30-day outcomes are similar.'

Society for Cardiovascular Angiography and Interventions/American College of Cardiology/Heart Failure Society of America/Society for Thoracic Surgeons (SCAI/ACC/HFSA/STS)
The 2015 consensus statement addressed IABPs, left atrial (LA)-to-aorta assist device (e.g., TandemHeart), left ventricle (LV)-to-aorta assist devices (e.g., Impella), extracorporeal membrane oxygenation (ECMO), and methods of right-sided support (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 (e.g., sole remaining vessel, left main disease, or 3-vessel disease) (Maini et al. 2012; O'Neill et al. 2012; Alli et al. 2021).

The statement reviews the use of MCS in patients undergoing high-risk percutaneous intervention, those with cardiogenic shock, and those with acute decompensated heart failure:

1. "Percutaneous MCS provides superior hemodynamic support compared to pharmacologic therapy. This is particularly apparent for the Impella and Tandem-Heart devices. These devices should remain available clinically and be appropriately reimbursed.
2. Patients in cardiogenic shock represent an extremely high-risk group in whom mortality has remained high despite revascularization and pharmacologic therapies. Early placement of an appropriate MCS may be considered in those who fail to stabilize or show signs of improvement quickly after initial interventions.

3. MCS may be considered for patients undergoing high-risk PCI, such as those requiring multivessel, left main, or last patent conduit interventions, particularly if the patient is inoperable or has severely decreased ejection fraction or elevated cardiac filling pressures.
4. In the setting of profound cardiogenic shock, IABP is less likely to provide benefit than continuous flow pumps including the Impella CP and TandemHeart. ECMO may also provide benefit, particularly for patients with impaired respiratory gas exchange.
5. Patients with acute decompensated heart failure may benefit from early use of percutaneous MCS when they continue to deteriorate despite initial interventions. MCS may be considered if patients are candidates for surgically implanted VADs or if rapid recovery is expected (e.g., fulminant myocarditis or stress-induced cardiomyopathy).
6. When oxygenation remains impaired, adding an oxygenator to a TandemHeart circuit or use of ECMO should be considered based upon local availability.
7. There are insufficient data to support or refute the notion that routine use of MCSs as an adjunct to primary revascularization in the setting of large acute myocardial infarction is useful in reducing reperfusion injury or infarct size. Exploratory studies are underway.
8. MCSs may be used for failure to wean off cardiopulmonary bypass, considered as an adjunct to high-risk electrophysiologic procedures when prolonged hypotension is anticipated, or rarely, for valvular interventions.
9. Severe biventricular failure may require use of both right- and left-sided percutaneous MCS or veno-arterial ECMO. Certain patients may respond to LVAD implantation with inotropes and/or pulmonary vasodilators to support the right heart. MCS may also be considered for isolated acute RVF complicated by cardiogenic shock.
10. Registries and randomized controlled trials comparing different strategies in different clinical scenarios are critically needed."

National Institute for Health and Clinical Excellence (NICE)

Interventional Procedure Guidance 633. Percutaneous Insertion of a Temporary Heart Pump for Left Ventricular Hemodynamic Support in High-Risk PCI (2018)

A 2018 interventional procedure guidance on high-risk PCI stated that a subset of high-risk patients (e.g., unprotected left main disease, last remaining vessel, multi-vessel disease, poor LV function, ongoing myocardial ischemia, cardiogenic shock) may benefit from heart support during PCI. The aim of heart support is to increase cardiac output, unload the ventricle, and improve blood flow to maintain hemodynamic stability which would minimize ischemia and reduce the risk of hemodynamic collapse during the procedure. PVADs have been proposed as an alternative to IABP or extra-corporeal pumps for this indication. NICE stated that the use of this technology may allow patients who would otherwise not be able to undergo PCI to have PCI. However, it is recognized that the current evidence to support the use of pVADs during high-risk PCI shows 'serious, infrequent but well-recognized safety concerns.' It is also noted that the evidence on efficacy is limited in quality. The guidance advises that this procedure should only be used with special arrangements for clinical governance, consent, and audit or research.

Medtech Innovation Briefing [MIB89]: Impella 2.5 for Hemodynamic Support During High-risk PCI (2016)

The MIB states that the Impella 2.5 could be used as an alternative to an IABP to provide hemodynamic support for suitable individuals before, during, or after elective or urgent high-risk PCI.

SUPPLEMENTAL INFORMATION

Cardiogenic shock: A primary cardiac disorder characterized by a low cardiac output state of circulatory failure that results in end-organ hypoperfusion and tissue hypoxia. Cardiogenic shock remains the most common cause of mortality in patients with acute MI and occurs in 5–10% of patients with acute MI (van Diepen et al. 2017). Mortality in this population has been reported to be at least 40% to 50% and a higher mortality rate depending on the population studied. (Werdan K et al. 2014; Thiele et al. 2015).

CODING & BILLING INFORMATION

CPT Codes

CPT	Description
33990	Insertion of ventricular assist device, percutaneous including radiological supervision and interpretation; left heart, arterial access only
33991	Insertion of ventricular assist device, percutaneous including radiological supervision and interpretation; left heart, both arterial and venous access, with transseptal puncture
33992	Removal of percutaneous left heart ventricular assist device, arterial or arterial and venous cannula(s), at separate and distinct session from insertion
33993	Repositioning of percutaneous right or left heart ventricular assist device with imaging guidance at separate and distinct session from insertion
33995	Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; right heart, venous access only
33997	Removal of percutaneous right heart ventricular assist device, venous cannula, at separate and distinct session from insertion

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

12/14/2022 Updated verbiage, National Coverage Determination. No changes to criteria.
12/8/2021 Policy reviewed and revised. IRO Peer Review: 11/30/2021; 12/1/2021. Practicing physician board-certified in Cardiovascular Disease, Interventional Cardiology; Cardiovascular Disease. Notable revisions include:
- Addressed right heart failure indication, added clinical criteria (#3d: Impella RP System and Impella 5.5 with SmartAssist and relevant clinical literature
- Criteria #2 revised from “4-6 hours” to “14 days” according to approved indication
- Revised criteria #3 from ‘refractory cardiogenic shock’ TO ‘Cardiogenic shock, as an alternative to IABP; or cardiogenic shock refractory to medications (vasopressors and inotropes) with/without IABP;’
- Added informational note for ‘electrophysiological procedures’ and ‘high-risk PCI’
- Notable revisions from medical literature include: Added AATS/International Society for Heart and Lung Transplantation guidelines; NICE (Interventional Procedure Guidance)

6/8/2021 Coding reviewed by K. O’Brien, coder. Added two CPT codes: 33995, 33997.
12/10/2019 Policy reviewed, no changes. IRO review 7/17/19. Practicing MD board certified in Internal Medicine, Cardiovascular Disease. Updated the contraindication section based on FDA information. Added one additional FDA approval for the Impella 5.5 SmartAssist.
6/22/2017 Policy reviewed. No changes to criteria.
3/8/2018 Policy reviewed. No changes to criteria.
7/27/2016 Policy was reviewed and updated. No changes to criteria. Summary of medical evidence and reference sections were updated.
12/16/2015 Policy reviewed. No changes to criteria.
2/27/2013 New Policy.

REFERENCES

Government Agencies

1. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database. National coverage determination (NCD) – ventricular assist devices (20.9.1) version 2. Available from CMS
2. Food and Drug Administration (FDA).
   a. Impella 2.5 System. Summary of Safety and Effectiveness Data (SSED). Premarket Approval Application (PMA) No. P140003. Silver Spring, MD: FDA; March 23, 2015.
   b. Impella Recover LP 2.5 Percutaneous Cardiac Support System. 510(k) Summary K016723. Silver Spring, MD: FDA; May 30, 2008.
   c. Impella RP System. Summary of Safety and Probable Benefit. Humanitarian Device Exemption (HDE) No. H140001. Silver Spring, MD: FDA; January 23, 2015.
   d. Impella 5.0. 510(k) Summary. 501(k) No. K083111. Silver Spring, MD: FDA; April 16, 2009.

3. Food and Drug Administration (FDA). Global unique device identification database (GUDID). National Library of Medicine (NLM): AccessGUDID [website]. Available here. Accessed December 2022.

Peer Reviewed Publications

1. Ait Ichou J, Larivée N, Eisenberg MJ, et al. The effectiveness and safety of the Impella ventricular assist device for high-risk percutaneous coronary interventions: A systematic review. Catheter Cardiovasc Interv. 2018 Jun;91(7):1250-1260. Doi: 10.1002/ccd.27316. Epub 2017 Sep 20. PMID: 28941078.
2. Alli, O.O., Singh, I.M., Holmes, D.R., Jr., Pulido, J.N., Park, S.J. and Rihal, C.S. Percutaneous left ventricular assist device with TandemHeart for high-risk percutaneous coronary intervention: The Mayo Clinic experience. Cathet. Cardiovasc. Intervent., 2012 Nov 1;80(5):728-34. doi: 10.1002/ccd.23465. Epub 2012 Feb 29. PMID: 22378485.
3. Anderson MB, Goldstein J, Milano C, et al. Benefits of a novel percutaneous ventricular assist device for right heart failure: The prospective RECOVER RIGHT study of the Impella RP device. J Heart Lung Transplant. 2015 Dec;34(12):1549-60. doi: 10.1016/j.healun.2015.08.018. Epub 2015 Sep 8. PMID: 26681124.
4. Batsides G, Massaro J, Cheung A et al. Outcomes of Impella 5.0 in Cardiogenic Shock: A Systematic Review and Meta-analysis. Innovations (Phila). 2018 Jul/Aug;13(4):254-260.
5. Briasoulis A, Telila T, Palla M, et al. Meta-analysis of usefulness of percutaneous left ventricular assist devices for high-risk percutaneous coronary interventions. Am J Cardiol. 2016;118(3):369-375.
6. Burkhoff D, Cohen H, Brunckhorst C, O'Neill WW; TandemHeart Investigators Group. A randomized multicenter clinical study to evaluate the safety and efficacy of the TandemHeart percutaneous ventricular assist device versus conventional therapy with intraaortic balloon pumping for treatment of cardiogenic shock. Am Heart J. 2006;152(3):469.e1-469.e8.
7. Burkhoff D, O'Neill W, Brunckhorst C, et al. Feasibility study of the use of the TandemHeart percutaneous ventricular assist device for treatment of cardiogenic shock. Catheter Cardiovasc Interv. 2006 Aug;68(2):211-7. doi: 10.1002/ccd.20796. PMID: 16819767.
8. Cheng JM, den Uil CA, Hoeks SE, van der Ent M, Jewbali LS, van Domburg RT, Serruys PW. Percutaneous left ventricular assist devices vs. intra-aortic balloon pump counterpulsation for treatment of cardiogenic shock: a meta-analysis of controlled trials. Eur Heart J. 2009 Sep;30(17):2102-8.
9. Kovacic JC, Kini A, Banerjee S, Dangas G, Massaro J, Mehran R, et al. Patients with 3-vessel coronary artery disease and impaired ventricular function undergoing PCI with Impella 2.5 hemodynamic support have improved 90-day outcomes compared to intra-aortic balloon pump: a sub-study of the PROTECT II trial. J Interv Cardiol. 2015 Feb;28(1):32-40.
10. Maini B, Naidu SS, Mulukutla S et al. Real-world use of the Impella 2.5 circulatory support system in complex high-risk percutaneous coronary intervention: the USpella Registry. Catheter Cardiovasc Interv. 2012 Nov 1;80(5):717-25. doi: 10.1002/ccd.23403. Epub 2012 Apr 25.
11. O'Neill WW, Kleiman NS, Moses J, et al. A Prospective, Randomized Clinical Trial of Hemodynamic Support With Impella 2.5 Versus Intra-Aortic Balloon Pump in Patients Undergoing High-Risk Percutaneous Coronary Intervention: The PROTECT II Study. Circulation. 2012 Oct 2;126(14):1717-27.
12. Ouweneel DM, Eriksen E, Sjauw KD, et al. Percutaneous mechanical circulatory support versus intra-aortic balloon pump in cardiogenic shock after acute myocardial infarction. *J Am Coll Cardiol.* 2017;69(3):278-287.
13. Rios SA, Bravo CA, Weinreich M et al. Meta-Analysis and Trial Sequential Analysis Comparing Percutaneous Ventricular Assist Devices Versus Intra-Aortic Balloon Pump During High-Risk Percutaneous Coronary Intervention or Cardiogenic Shock. Am J Cardiol. 2018 Oct 15;122(8):1330-1338. Doi: 10.1016/j.amjcard.2018.07.011. Epub 2018 Jul 24
14. Romeo F, Acconcia MC, Sergi D, et al. Percutaneous assist devices in acute myocardial infarction with cardiogenic shock: Review, meta-analysis. World J Cardiol. Jan 26 2016; 8(1):98-111.
15. Shah R, Thomson A, Atianzar K, Somma K, Mehra A, Clavijo L, et al. Percutaneous left ventricular support for high-risk PCI and cardiogenic shock: who gets what? Cardiovasc Revasc Med. 2012 MarApr;13(2):101-5.
16. Seyfarth M, Sibbing D, Bauer I, et al. A randomized clinical trial to evaluate the safety and efficacy of a percutaneous left ventricular assist device versus intra-aortic balloon pumping for treatment of cardiogenic shock caused by myocardial infarction. J Am Coll Cardiol. 2008;52(19):1584-1588.
17. Thiele H, Sick P, Boudriot E, et al, Randomized comparison of intra-aortic balloon support with a percutaneous left ventricular assist device in patients with revascularized acute myocardial infarction complicated by cardiogenic shock. Eur Heart J. 2005;26(13):1276-1283.
18. Thiele H, Jobs A, Ouweneel DM, Henriques JPS, Seyfarth M, Desch S, et al. Percutaneous short-term active mechanical support devices in cardiogenic shock: a systematic review and collaborative metaanalysis of randomized trials. Eur Heart J. 2017 Dec 14;38(47):3523-3531.
19. Thomas JL, Al-Ameri H, Economides C, et al. Use of a percutaneous left ventricular assist device for high-risk cardiac interventions and cardiogenic shock. J Invasive Cardiol. 2010 Aug;22(8):360-4.

National and Specialty Organizations

1. American College of Cardiology Foundation/American Heart Association/Society for Cardiovascular Angiography and Interventions
   a. Levine G, Bates E, Blankenship J, et al. 2011 ACCF/AHA/SCAI guideline for percutaneous coronary 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.
   b. Levine G, Bates E, Blankenship J. et al.; ACCF/AHA Task Force on Practice Guidelines. 2015 ACC/AHA/SCAI focused update on primary percutaneous coronary intervention for patients with ST-elevation myocardial infarction: An update of the 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention and the 2013 ACCF/AHA Guideline for the Management of ST-Elevation Myocardial Infarction. [published correction appears in *J Am Coll Cardiol*. March 29, 2016;67(12):1506]. *J Am Coll Cardiol*. 2016;67(10):1235-1250. doi:10.1016/j.jacc.2015.10.005.

2. American College of Cardiology (ACC)/American Heart Association (AHA)/Heart Failure Society of America (HFSA)
   a. Yancy CW, Jessup M, Bozkurt B, et al. 2016 ACC/AHA/HFSA focused update on new pharmacological therapy for heart failure: An update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Failure Society of America. J Am Coll Cardiol. 2016 Sep 27;68(13):1476-1488. Doi: 10.1016/j.jacc.2016.05.011. Epub 2016 May 20. Erratum in: J Am Coll Cardiol. 2016 Sep 27;68(13):1495. PMID: 27216111.
   b. van Diepen S, Katz JN, Albert NM, Henry TD, Jacobs AK, Kapur NK, Kilic A, Menon V, Ohman EM, Sweitzer NK, Thiele H, Washam JB, Cohen MG; American Heart Association Council on Clinical Cardiology; Council on Cardiovascular and Stroke Nursing; Council on Quality of Care and Outcomes Research; and Mission: Lifeline. Contemporary management of cardiogenic shock: A scientific statement from the American Heart Association. Circulation. 2017 Oct 17;136(16):e232-e268. doi: 10.1161/CIR.0000000000000525. Epub 2017 Sep 18. PMID: 28923988.

3. National Institute for Health and Clinical Excellence (NICE)
   a. Interventional procedure guidance 633. Percutaneous insertion of a temporary heart pump for left ventricular haemodynamic support in high-risk percutaneous coronary interventions. London, UK: NICE; 2018 Nov. Available from NICE. Accessed November 2022.
   b. Impella 2.5 for hemodynamic support during high-risk percutaneous coronary interventions. November 2016. Available from NICE.

4. Society for Cardiovascular Angiography and Interventions (SCAI); Heart Failure Society of America (HFSA); Society for Thoracic Surgeons (STS); American Heart Association (AHA); American College of Cardiology (ACC).
   - Rihal CS, Naidu SS, Givertz MM, et al. 2015 SCAI/ACC/HFSA/STS clinical expert consensus statement on the use of percutaneous mechanical circulatory support devices in cardiovascular care (endorsed by the AHA, the Cardiological Society of India, and Sociedad Latino Americana de Cardiología Intervencionista; Affirmation of value by the Canadian Association of Interventional Cardiology-Association Canadienne de Cardiologie d'Intervention). Catheter Cardiovasc Interv. 2015;85(7):1112-1114. Available here and here. Accessed November 2021.

Evidence Based Reviews and Publications

1. Abiomed. Heart recovery: Products and services. Available here. Accessed November 2022.
2. DynaMed. Cardiogenic shock (record no. *T115657*). Available from DynaMed. Updated November 30, 2018.
3. Jeevanandam V, Eisen HJ, Pinto DS. Fitzsimons M, Nicoara A, Yasmin M. Short-term mechanical circulatory support: Initiation and management considerations. Available from UpToDate. Updated May 28, 2021. Registration and login required.

Other Peer Reviewed and National Organization Publications (used in the development of this policy)

1. Alasnag MA, Gardi DO, Elder M, et al. Use of the Impella 2.5 for prophylactic circulatory support during elective high-risk percutaneous coronary intervention. Cardiovasc Revasc Med. 2011 Sep-Oct;12(5):299-303.
2. Amin AP, Spertus JA, Curtis JP, et al. The evolving landscape of Impella use in the United States among patients undergoing percutaneous coronary intervention with mechanical circulatory support. Circulation. 2020 Jan 28;141(4):273-284. doi: 10.1161/CIRCULATIONAHA.119.044007. Epub 2019 Nov 17. PMID: 31735078.
3. FBaumann S, Werner N et al. Indication and short-term clinical outcomes of high-risk percutaneous coronary intervention with microaxial Impella pump: results from the German Impella® registry. Clin Res Cardiol. 2018 Aug;107(8):653-657. doi: 10.1007/s00392-018-1230-6. Epub 2018 Mar 8.
4. Burzotta F, Paloscia L, Trani C, et al. Feasibility and long-term safety of elective Impella-assisted high-risk percutaneous coronary intervention: a pilot two-centre study. J Cardiovasc Med (Hagerstown). 2008;9(10):1004-1010.
5. Cohen MG, Matthews R, Maini B et al. Percutaneous left ventricular assist device for high-risk percutaneous coronary interventions: Real-world versus clinical trial experience. Am Heart J. 2015 Nov;170(5):872-9. doi: 10.1016/j.ahj.2015.08.009. Epub 2015 Aug 15.
6. Dangas GD, Kini AS, Sharma SK, et al. Impact of hemodynamic support with Impella 2.5 versus intra-aortic balloon pump on prognostically important clinical outcomes in patients undergoing high-risk percutaneous coronary intervention (from the PROTECT II randomized trial). Am J Cardiol. Jan 15 2014; 113(2):222-228.
7. Dhruva SS, Ross JS, Mortazavi BJ, et al. Association of Use of an Intravascular Microaxial Left Ventricular Assist Device vs Intra-aortic Balloon Pump With In-Hospital Mortality and Major Bleeding Among Patients with Acute Myocardial Infarction Complicated by Cardiogenic Shock. JAMA. 2020;323(8):734–745. doi:10.1001/jama.2020.0254.
8. European Society of Cardiology (ESC)/ European Association for Cardio-Thoracic Surgery (EACTS)
   a. 2014 Guidelines on myocardial revascularization: The Task Force on Myocardial Revascularization of the ESC and the EACTS: Developed with the special contribution of the European Association of Percutaneous Cardiovascular Interventions (EAPCI). European Heart Journal. 2014;35(37):2541-2619.
   b. 2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure: The Task Force for the diagnosis and treatment of acute and chronic heart failure of the ESC. Developed with the special contribution of the Heart Failure Association (HFA) of the ESC. Eur J Heart Fail. 2016 Aug;18(8):891-975.
   c. 2018 ESC/EACTS Guidelines on myocardial revascularization. The Task Force on myocardial revascularization of the ESC and EACTS. European Heart Journal, Volume 40, Issue 2, 07 January 2019, pages 87–165.
   d. 2017 ESC Guidelines for the management of acute myocardial infarction in patients presenting with ST-segment elevation: The Task Force for the management of acute myocardial infarction in patients presenting with ST-segment elevation of the ESC. European Heart Journal, Volume 39, Issue 2, 07 January 2018, pages 119–177.
9. Hayes. Available from Hayes.
   a. Impella 2.5 System (Abiomed Inc.) for cardiac support in patients undergoing high-risk percutaneous coronary intervention (PCI). Published October 2018. Archived October 2020.
   b. Impella 5.0 (Abiomed Inc.) for emergent hemodynamic support in patients with cardiogenic shock. Published September 2015. Updated June 2017. Archived October 2018.
   c. Impella 2.5 System (Abiomed Inc.) for emergent hemodynamic support in patients with cardiogenic shock. Published September 2015. Updated July 2017. Archived October 2018.
   d. Impella CP (Abiomed) for use in adult patients with cardiogenic shock. Published August 2017. Updated August 2018. Archived Sept. 2020.
   e. Impella 5.5 (Abiomed, Inc.) for the temporary treatment of cardiogenic shock. Published October 2020. Archived November 1, 2021.
10. Henriques JP, Ouweneel DM, Naidu SS, et al. Evaluating the learning curve in the prospective randomized clinical trial of hemodynamic support with Impella 2.5 versus intra-aortic balloon pump in patients undergoing high-risk percutaneous coronary intervention: a prespecified subanalysis of the PROTECT II study. Am Heart J. 2014;167(4):472-479.e5.
11. Henriques JP, Remmelink M, Baan J Jr, et al. Safety and feasibility of elective high-risk percutaneous coronary intervention procedures with left ventricular support of the Impella Recover LP 2.5. Am J Cardiol. 2006;97(7):990-992.
12. Garan AR1, Takeda K et al. Prospective Comparison of a Percutaneous Ventricular Assist Device and Venoarterial Extracorporeal Membrane Oxygenation for Patients With Cardiogenic Shock Following Acute Myocardial Infarction. J Am Heart Assoc. 2019 May 7;8(9):e012171. doi: 10.1161/JAHA.119.012171.
13. Kar B, Gregoric ID, Basra SS, Idelchik GM, Loyalka P. The Percutaneous Ventricular Assist Device in Severe Refractory Cardiogenic Shock. J Am Coll Cardiol. 2011;57:688-696.
14. Kovacic JC, Nguyen HT, Karajgikar R, Sharma SK, Kini AS. The Impella 2.5 and TandemHeart Ventricular Assist Devices are Safe and Associated With Equivalent Clinical Outcomes in Patients Undergoing High-Risk Percutaneous Coronary Intervention. Catheter Cardiovasc Interv. Catheter Cardiovasc Interv. 2011 Jan 13.
15. Lauten A, Engström AE, Jung C, et al. Percutaneous left-ventricular support with the Impella-2.5-assist device in acute cardiogenic shock: results of the Impella-EUROSHOCK-Registry. Circ Heart Fail. 2013;6(1):23-30.
16. Manzo-Silberman S, Fichet J, Mathonnet A, et al. Percutaneous left ventricular assistance in post cardiac arrest shock: comparison of intra-aortic blood pump and IMPELLA Recover LP2.5. Resuscitation. 2013;84(5):609-615.
17. Naidu, S. Novel. Percutaneous Cardiac Assist Devices: The Science of and Indications for Hemodynamic Support. Circulation, 2011: 125:533-543.
18. O'Neill WW, Schreiber T, Wohns DH, et al. The current use of Impella 2.5 in acute myocardial infarction complicated by cardiogenic shock: results from the USpella Registry. J Interv Cardiol. 2014;27(1):1-11.
19. Remmelink M, Sjauw KD, Henriques JP, et al. Effects of left ventricular unloading by Impella recover LP2.5 on coronary hemodynamics. Catheter Cardiovasc Interv. 2007;70(4):532-537.

20. Schwartz BG, Ludeman DJ, Mayeda GS, et al. High-risk percutaneous coronary intervention with the TandemHeart and Impella devices: a single-center experience. J Invasive Cardiol. 2011 Oct;23(10):417-24.
21. Shah AP, Retzer EM, Nathan S, et al. Clinical and economic effectiveness of percutaneous ventricular assist devices for high-risk patients undergoing percutaneous coronary intervention. J Invasive Cardiol. 2015;27(3):148-154.
22. Shavelle DM, Banerjee S, Maini B et al. Comparison of Outcomes of Percutaneous Coronary Intervention on Native Coronary Arteries Versus on Saphenous Venous Aorta Coronary Conduits in Patients With Low Left Ventricular Ejection Fraction and Impella Device Implantation Achieved or Attempted (from the PROTECT II Randomized Trial and the cVAD Registry). Am J Cardiol. 2018 Sep 15;122(6):966-972. doi: 10.1016/j.amjcard.2018.06.013. Epub 2018 Jun 21.
23. Sieweke JT, Pfeffer TJ et al. Cardiogenic shock complicating peripartum cardiomyopathy: Importance of early left ventricular unloading and bromocriptine therapy. . Eur Heart J Acute Cardiovasc Care. 2018 May 1:2048872618777876. doi: 10.1177/2048872618777876. [Epub ahead of print]
24. Tempelhof MW, Klein L, Cotts WG, et al. Clinical experience and patient outcomes associated with the TandemHeart percutaneous transseptal assist device among a heterogeneous patient population. ASAIO J. 2011 Jul-Aug;57(4):254-61.
25. Thiele H, Ohman EM, Desch S, Eitel I, de Waha S. Management of cardiogenic shock.Eur Heart J. 2015; 36:1223–1230. doi: 10.1093/eurheartj/ehv051
26. Valgimigli M, Steendijk P, Serruys PW, et al. Use of Impella Recover LP 2.5 left ventricular assist device during high-risk percutaneous coronary interventions; clinical, haemodynamic and biochemical findings. EuroIntervention. 2006:2(1):91-100.
27. van Diepen S, Katz JN, Albert NM, Henry TD, Jacobs AK, Kapur NK, Kilic A, Menon V, Ohman EM, Sweitzer NK, Thiele H, Washam JB, Cohen MG. Contemporary management of cardiogenic shock: a scientific statement from the American Heart Association. Circulation. 2017; 136:e232–e268.
28. Vranckx P, Meliga E, De Jaegere PP et al. The TandemHeart, percutaneous transseptal left ventricular assist device: a safeguard in high-risk percutaneous coronary interventions. The six-year Rotterdam experience. EuroIntervention. 2008 Nov;4(3):331-7.
29. Vranckx P, Schultz CJ, Valgimigli M, et al. Assisted circulation using the TandemHeart during very high-risk PCI of the unprotected left main coronary artery in patients declined for CABG. Catheter Cardiovasc Interv. 2009 Aug 1;74(2):302-10
30. Werdan K, Gielen S, Ebelt H, Hochman JS. Mechanical circulatory support in cardiogenic shock.Eur Heart J. 2014; 35:156–167. Doi: 10.1093/eurheartj/eht248

APPENDIX

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*

Centers for Medicare & Medicaid Services (CMS)

A National Coverage Determination (NCD) was updated 12/01/2020 and indicates that surgically attached ventricular assist devices for post-cardiotomy, bridge-to-recovery, bridge-to-transplant, and destination therapy is covered. The NCD does not provide coverage ofpercutaneously inserted ventricular assist devices, VADs for right ventricular support, biventricular support, beneficiaries under 18, those with complex congenital heart disease or those with acute heart failure.