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

Last Approval: 12/13/2023
Next Review Due By: December 2024

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, are only intended for short term use, 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 for 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. pVAD devices, specifically the Impella devices, are not intended for use in conjunction with IABP or Extracorporeal Membrane Oxygenation (ECMO) therapy, as it is associated with higher adverse events (Cappannoli et al 2023; Bochaton et al 2020).

Regulatory Status

Adverse Events associated with pVADs 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.

Impella® Products (Abiomed Inc)
Abiomed Inc received its original FDA approval via Premarket Approval for the Impella 2.5 system for left heart support in March 2015, and Impella RP for right heart support in 2017. Since these approvals there have been many additions and/or changes to the devices and subsequent premarket supplemental approvals have been issued for the Impella devices including labeling changes, post-approval study protocols, and manufacturing process changes.

The indication of cardiogenic shock is intended for patients with ongoing cardiogenic shock that occurs within 48 hours following acute myocardial infarction, open heart surgery, or in the setting of cardiomyopathy (including peripartum cardiomyopathy), or myocarditis because of isolated left ventricle failure, which is not responsive to optimal medical management and conventional treatment measures.

The indication of High-Risk Percutaneous Coronary Intervention (HRPCI) is intended for use during HRPCI performed in elective or urgent, hemodynamically stable patients with severe coronary artery disease, when a heart team, including a cardiac surgeon, has determined HRPCI is the appropriate therapeutic option.

Product Specific Information

- Impella 2.5 System: FDA approved March 2015 under product code OZD as a temporary non-roller type left heart support blood pump. The product's FDA approved indications are HRPCI and cardiogenic shock and can be used for up to 6 hours when utilized for HRPCI, and up to 4 days when utilized for cardiogenic shock. This specific device is inserted percutaneously via femoral or axillary access and does not come with SmartAssist.
- Impella CP: FDA approved in 2016 under product code OZD as a temporary non-roller type left heart support blood pump. The product's FDA approved indications are HRPCI and cardiogenic shock and can be used for

up to 6 hours when utilized for HRPCI, and up to 4 days when utilized for cardiogenic shock. This specific device is inserted percutaneously via femoral or axillary access and can come with SmartAssist.

- Impella RP/RP Flex: FDA approved in 2017 under product code PYX as a temporary non-roller type right heart support blood pump. The products FDA approved indication is for right heart failure or decompensation and can be used for up to 14 days. It is intended for patients with a body surface area ≥1.5 m2, who develop acute right heart failure or decompensation following left ventricular assist device (LVAD) implantation, MI, heart transplant, or open-heart surgery. This specific device is inserted percutaneously via femoral vein to pulmonary artery and can come with SmartAssist.
- Impella 5.0: FDA approved in 2018 under product code OZD as a temporary non-roller type left heart support blood pump. This product's FDA approved indication is cardiogenic shock and can be used for up to 14 days. This specific device is inserted via femoral cutdown or axillary access and does not come with SmartAssist.
- Impella LD: FDA approved in 2018 under product code OZD as a temporary non-roller type left heart support blood pump. This product's FDA approved indication is cardiogenic shock and can be used for up to 14 days. This specific device is directly inserted into the ascending aorta and does not come with SmartAssist.
- Impella 5.5: FDA approved in 2019 under product code OZD as a temporary non-roller type left heart support blood pump. This product's FDA approved indication is cardiogenic shock and can be used for up to 14 days. This specific device is inserted via axillary cutdown or directly into the ascending aorta and can come with SmartAssist.

COVERAGE POLICY

Percutaneous Ventricular Assist Devices (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. Intended use is for short term, up to 14 days, partial circulatory support; **AND**

3. Member meets **ONE** of the following clinical indications according to the labeling of pVAD:
   a. ST Segment Elevation Myocardial Infarction when unable to be stabilized with pharmacological ionotropic therapy; **OR**
   b. 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 intra-aortic balloon pump (IABP); or cardiogenic shock refractory to medications (vasopressors and inotropes) with/without IABP; **OR**
   c. As an adjunct to High-Risk Percutaneous Coronary Intervention (HRPCI) in the following *high-risk patients undergoing invasive cardiac or **electrophysiological procedures who need circulatory support:
      i. Undergoing unprotected left main or last-remaining patent conduit vessel with ejection fraction less than 35%; **OR**
      ii. Severely depressed ejection fraction (≤ 35%) undergoing HRPCI of a vessel supplying a large territory; **OR**
      iii. ***Triple vessel disease with end diastolic ejection fraction less than 30%

   *The definition of HRPCI 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)'.

   **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.

   ***Triple vessel disease defined as at least one significant stenosis (e.g., 75% or greater stenosis by diameter) in all three major epicardial territories

4. For the Impella RP and Impella RP Flex System with SmartAssist ONLY: Member must have a body surface area

≥ 1.5 m **AND** meet **ONE** of the following indications:
a. Acute right heart failure; **OR**
b. Right heart failure decompensation following left ventricular assist device (LVAD) implantation; **OR**
c. 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 as pVADs may only be used short-term (for up to 14 days) with initial authorization only.

LIMITATIONS AND EXCLUSIONS
Device-specific contraindications (as applicable):

1. The Impella 2.5, Impella CP, Impella CP with SmartAssist, Impella 5.0, Impella 5.5, Impella 5.5 with SmartAssist and Impella LD are contraindicated for use in 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
   e. Moderate to severe aortic insufficiency (echocardiographic assessment of aortic insufficiency graded as ≥ +2)

2. The Impella 2.5, Impella CP, Impella CP with SmartAssist, Impella 5.0, Impella 5.5, Impella 5.5 with SmartAssist and Impella LD are contraindicated for use in patients experiencing the following conditions in the setting of cardiogenic shock:
   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

3. The Impella RP and Impella RP Flex with SmartAssist is contraindicated for use in patients experiencing **ANY** of the following conditions:
   a. Disorders of the pulmonary artery wall that would preclude placement or correct positioning of the Impella RP device
   b. Mechanical valves, severe valvular stenosis, or valvular regurgitation of the tricuspid or pulmonary valve
   c. Mural thrombus of the right atrium or vena cava
   d. Anatomic conditions precluding insertion of the pump
   e. Presence of a vena cava filter or caval interruption device, unless there is clear access from the femoral vein to the right atrium that is large enough to accommodate a 22 Fr catheter

The following are considered **experimental, investigational, and unproven** based on insufficient evidence:
1. Any indications other than those listed above
2. Impella devices used in conjunction with Venoartierial or Venovenous Extracorporeal Membrane Oxygenation and/or intra-aortic balloon pumps

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

High-Risk PCI
Del Rio-Pertuz et al. (2022) conducted a systematic review and meta-analysis evaluating the efficacy of mechanical circulatory support in patients with ST-elevation myocardial infarction complicated by cardiogenic shock. Mechanical

support included intra-aortic balloon pump (IABP), Impella devices, and Veno-arterial extracorporeal membrane oxygenation (VA-ECMO). Ten studies involving a total of 1,352 patients (956 IABP, 203 Impella, and 193 VA-ECMO) were included. While Impella and VA-ECMO started before high-risk percutaneous coronary intervention (HR-PCI) were significantly associated with a reduced risk of mortality compared to that started after HRPCI ([OR] 0.49, 95% CI 0.26-0.92, I2 = 0%, p = 0.03 and [OR] 0.29, 95% CI 0.14-0.62, I2 = 0%, p = 0.001, respectively), no difference in mortality was found using IABP before or after HRPCI ([OR] 1.77, 95% CI 0.77-1.61, I2 = 27%, p = 0.57). The authors stipulated that more rigorous studies were needed to validate these findings. This conclusion is supported by findings in a prospective, single center, observational study evaluating the outcomes of Impella initiation pre-HRPCI and post-HRPCI conducted by Hemradj et al. (2020). This 88-patient study revealed thirty-day cardiac mortality was significantly lower in the pre-PCI group, 19% versus 44.7% in the post-PCI group (HR 0.3, 95% CI 0.09-0.96, p = 0.042).

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 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 HRPCI, 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 left ventricle ejection fraction was low, ranging from 23%-37%, while the percentage of patients with previous myocardial infarction 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 were similar across groups. In most uncontrolled studies, the 30-day rates of all-cause mortality were low (range: 3.7%–10%), though rates of major adverse cardiac events 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.

O'Neill et al. (2012) conducted this prospective multicenter randomized trial (PROTECT II) to assess whether a HRPCI 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 of ≤ 35%, or with 3-vessel disease and left ventricular ejection fraction ≤ 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 adverse events at discharge or 30-day follow-up, whichever was longer. Between November 27, 2007, and December 6, 2010, 452 patients were enrolled. 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 adverse events 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 adverse events 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 adverse events did not reach statistical significance for the entire study, the analysis of 90-day events remains exploratory.

Cardiogenic Shock

Ardito et al. (2023) conducted a systematic literature review and meta-analysis comparing Impella devices versus VA-ECMO in the setting of cardiogenic shock. Within the period of 2017-2022, a total of 102 articles were included in the analysis. Most of the studies were observational with a retrospective design and four were randomized controlled trials, with an average sample size of 304 patients. Overall mortality was the most prominent primary outcome with results in favor of Impella. The overall mortality rate for patients treated with Impella were 43% at 30 days, 46% at 6 months, and 48% at 1 year; compared to VA- ECMO of 47% at 30 days, 61% at 6 months, and 52% at 1 year. There was no statistically significant difference in the percentage of patients successfully weaned from Impella or VA-ECMO therapy, both with values between 45-65%. Major bleeding occurred in 20% of patients treated with Impella vs 25% with VA-ECMO. Limb ischemia occurred in 6% of patients treated with Impella vs 10% with VA-ECMO. The authors also found a longer support duration is observed for VA-ECMO (4.47 days, CI 95%: 2.93–6.00), compared to Impella

(3.23 days, CI 95%: 1.99–4.48). Risk of bias was assessed using tools specifically designed for cohort studies and RCTs [26,27]. In general, the selected studies perform well in terms of risk of bias, scoring "Yes" in most fields on the checklists; however, overall risk of bias was low for this systematic review. The authors concluded the evidence highlighted Impella's validity as an intervention in the setting of cardiogenic shock and may offer better clinical outcomes over VA-ECMO; however further data needs to be collected to validate these findings. Batchelor et al. (2022) conducted a systematic review and meta-analysis analyzing VA-ECMO versus Impella devices with similar findings.

Panuccio et al. (2022) conducted a systematic review and meta-analysis exploring the clinical outcomes of Impella devices in the setting of cardiogenic shock. A total of 33 studies were included in the analysis for a total of 5203 patients admitted for cardiogenic shock and treated with Impella devices. Impella devices had a 47% short term mortality rate with meta-regression analysis showing the regression line of the impact exerted by Impella on mortality crossed the zero-effect line by the mean age of 67 years, which suggests no benefit for older age. The use of higher mechanical circulatory support, utilizing Impella 5.0 or Impella CP, is associated with lower short-term mortality, highlighting the careful selection of adequate device size is key to clinical success. The authors also found that treating patients with Impella devices prior to HRPCI was associated with lower mortality rates. Adverse events analyzed were vascular access complications, which had a 6.4% occurrence rate, and major bleeding, which occurred in 16.4% of cases. Bias was demonstrated to be a mild to moderate risk, with moderate to severe heterogeneity; and the main limitation of the analysis being that all included studies were retrospective. Ultimately the authors concluded that large prospective clinical trials are needed to have a definitive picture of the clinical impact of Impella devices used in cardiogenic shock.

Karami et al. (2021) conducted a 5-year follow-up of the multicenter, randomized IMPRESS in Severe Shock trial (NTR3450) after initial randomization. A total of 48 ST-elevation myocardial infarction patients with severe cardiogenic shock undergoing immediate revascularization were randomized to be treated with Impella CP (n = 24) or IABP (n = 24). All-cause mortality, functional status, and occurrence of major adverse cardiac and cerebrovascular events (death, myocardial re-infarction, repeat percutaneous coronary intervention, coronary artery bypass grafting, and stroke) were assessed in the follow up to reveal five-year mortality was 50% (n = 12/24) in Impella patients vs. 63% (n = 15/24) in IABP patients (relative risk 0.87, 95% confidence interval 0.47-1.59, P = 0.65). Major adverse cardiac and cerebrovascular events occurred in 50% of the Impella patients vs. 79% of the IABP patients (P = 0.07). All survivors except for one were in New York Heart Association Class I/II [Impella n = 10 (91%) and IABP n = 7 (100%), P = 1.00] and none of the patients had residual angina. There were no differences in left ventricular ejection fraction between the groups (Impella 52 ± 11% vs. IABP 48 ± 10%, P = 0.53). The authors concluded this study supported the short-term data and other long term cardiogenic shock trials evidence that there is little to no statistically significant difference between percutaneous mechanical circulatory support using Impella devices and IABP therapy.

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%).

Acute Right Sided Heart Failure

Anderson et al. (2015) conducted 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 the 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 myocardial infarction 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 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, myocardial infarction, heart transplant, or open-heart surgery.

National and Specialty Organizations

American Association for Thoracic Surgery (AATS)/International Society for Heart and Lung Transplantation published guidelines 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' (Kirklin et al. 2020).

Society for Cardiovascular Angiography and Interventions/American College of Cardiology/Heart Failure Society of America/Society for Thoracic Surgeons (SCAI/ACC/HFSA/STS) released a consensus statement addressed IABPs, left atrial-to-aorta assist device (e.g., TandemHeart), left ventricle-to-aorta assist devices (e.g., Impella), ECMO, and methods of right-sided support (Rihal et al. 2015).

One of the suggested indications for percutaneous mechanical circulatory support (MCS) is for patients undergoing HRPCI, especially if the patient is inoperable or has a low left ventricle ejection fraction (< 20% to 30%) and complex coronary artery disease involving a large territory (e.g., sole remaining vessel, left main disease, or 3-vessel disease).

The statement reviews the use of MCS in patients undergoing HRPCI, 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 HRPCI, 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 benefits, 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 is insufficient data to support or refute the notion that routine use of MCS 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. MCS 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 VA-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) published the *Interventional Procedure Guidance 633. Percutaneous Insertion of a Temporary Heart Pump for Left Ventricular Hemodynamic Support in High-Risk PCI (2018)* stating 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 HRPCI. 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 have the procedure to undergo HRPCI; however, it is recognized that the current evidence to support the use of pVADs during HRPCI 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.

NICE's *Medtech Innovation Briefing [MIB89]: Impella 2.5 for Hemodynamic Support During High-risk PCI (2016)* 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 HRPCI.

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology) 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

12/13/2023	Policy reviewed and coverage criteria updated to include contraindications for Impella RP & RP Flex, and Impella therapy used in conjunction with ECMO or IABP. TandemHeart information removed. Overview, Summary of medical evidence, and references updated. IRO Peer Review November 2023 by a practicing physician board certified in Cardiology.
12/14/2022	Policy reviewed, no changes to coverage criteria, updated references and summary of medical evidence.
12/08/2021	Policy reviewed and revised. IRO Peer Review: 11/30/2021 & 12/1/2021 by practicing physician board-certified in Cardiovascular Disease, Interventional Cardiology; Cardiovascular Disease. Notable criteria revisions include: Addressed right heart failure indication, added clinical criteria (#3d: Impella RP System and Impella 5.5 with SmartAssist and relevant clinical literature; partial circulatory support short-term use updated to "up to 14 days"; 'Refractory cardiogenic shock' revised TO 'Cardiogenic shock, as an alternative to IABP; or cardiogenic shock refractory to medications (vasopressors and inotropes) with/without IABP. Updated summary of medical evidence.
06/08/2021	Coding reviewed by K. O'Brien, coder. Added two CPT codes: 33995, 33997.
12/10/2019	Policy reviewed, no changes to coverage criteria. IRO review 7/17/19 by a practicing physician 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.
06/22/2017	Policy reviewed, no changes to coverage criteria, updated references and summary of medical evidence.

03/08/2016 Policy reviewed, no changes to coverage criteria, updated references and summary of medical evidence.
07/27/2016 Policy reviewed, no changes to coverage criteria, updated references and summary of medical evidence.
12/16/2015 Policy reviewed, no changes to coverage criteria, updated references and summary of medical evidence.
02/27/2013 New Policy.

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