Molina Clinical Policy
Percutaneous Ventricular Assist Devices
Policy No. 132

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OVERVIEW

Cardiogenic shock (CS) is an acute, life-threatening condition defined as a state of tissue hypoperfusion and end organ dysfunction due to low cardiac output and is associated with a high rate of morbidity and mortality. Cardiogenic shock may be secondary to conditions such as acute myocardial infarction (MI), advanced decompensated heart failure (HF), fulminant myocarditis, or cardiac dysfunction post-cardiotomy. Temporary, mechanical circulatory assist devices may be used to restore and stabilize systemic perfusion. Additionally, patient undergoing a **high-risk percutaneous coronary interventions (HRPCIs)** may require and benefit from mechanical circulatory assist devices when there is high risk of hemodynamic collapse during the procedure (Bochaton et al. 2020; Jeevanandam & Eisen 2024).

Percutaneous ventricular assist devices (pVADs), placed via cardiac catheterization without the need for open-chest surgery, have been developed for short-term use in patients who require acute circulatory support, typically for conditions related to CS or during HRPCIs. While the intra-aortic balloon pump (IABP) is the most common short-term mechanical circulatory assist device, it's only capable of producing modest hemodynamic support and myocardial protection. Thus, other percutaneous circulatory devices have been developed and explored as alternatives.

Regulatory Status

pVADs are regulated by the FDA, as a temporary non-roller type heart support pump and Class III medical device. They are approved through the premarket approval (PMA). Adverse events associated with pVADs may include but are not limited to access site complications (e.g., bleeding, aneurysms, leg ischemia) and cardiovascular complications such as perforation, MI, stroke, or arrhythmias.

When used for CS, pVADs are generally intended for patients with ongoing CS that occurs within 48 hours following acute MI, open heart surgery, or in the setting of cardiomyopathy (including peripartum cardiomyopathy), or myocarditis, as a result of isolated ventricle failure not responsive to optimal medical and conventional management (e.g., volume loading and use of pressors or inotropes, with or without IABP). When used for HRCPIs, pVADs are intended for use during an elective or urgent HRCPI in hemodynamically stable patients with severe coronary artery disease (CAD) and when a heart team, including a cardiac surgeon, has determined HRPCI is the appropriate therapeutic option (Abiomed 2025).

The *Impella* system (Abiomed Inc.) is the primary pVAD on the market, with several models available for varying levels and durations of circulatory support. Certain models incorporate *SmartAssist* technology to provide real-time feedback about device position and hemodynamic performance. Impella systems are listed in the Premarket Approval Database; left side devices can be found under PMA P140003 and product code OZD, right side devices can be found under P170011 and product code PYX. The following includes product-specific information related to distinct, FDA-approved *Impella* systems:

- Impella 2.5 System: FDA-approved in 2015 as a temporary (≤ 6 hours) left heart support blood pump indicated for HRPCIs in patients with severe CAD and depressed left ventricular ejection fraction. In 2016, the device received supplemental approval for temporary ventricular support (≤ 4 days) for the treatment of ongoing CS that occurs immediately (< 48 hours) following acute MI or open-heart surgery as a result of isolated left

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ventricular failure that is not responsive to optimal medical management and conventional treatment. The device is inserted percutaneously via femoral or axillary access without SmartAssist.

- Impella CP: FDA-approved in 2016 as a temporary left heart support blood pump. Similarly to the Impella 2.5, the device is indicated for HRPCI (≤ 6 hours) and CS (< 4 days). The device has a higher flow rate than the 2.5 model, is inserted percutaneously via femoral or axillary access, and is available with or without SmartAssist.
- Impella RP/RP Flex: The Impella RP was FDA-approved in 2017 as a temporary (≤ 14 days) right heart support pump, indicated for patients with a body surface area ≥ 1.5 m^2 who develop acute right HF or decompensation following left VAD implantation, MI, heart transplant, or open-heart surgery. The device is inserted percutaneously via the femoral vein with SmartAssist. In 2022, the system received supplemental approval as the Impella RP Flex with SmartAssist and allows for placement via the internal jugular vein.
- Impella 5.0: FDA-approved in 2016 as a temporary left heart support blood pump, indicated for temporary ventricular support for the treatment of ongoing CS that occurs immediately (< 48 hours) following acute MI or open heart surgery as a result of isolated left ventricular failure that is not responsive to optimal medical management and conventional treatment. The system was originally approved for use ≤ 6 days but received supplemental approval in 2019 for use ≤ 14 days. The device is inserted via femoral cutdown or axillary access, does not come with SmartAssist, and has a higher flow capacity than previous models.
- Impella LD: FDA-approved in 2019 as a temporary (≤ 14 days) left heart support blood pump for CS. The device is directly inserted into the ascending aorta and does not come with SmartAssist.
- Impella 5.5: FDA-approved in 2019 as a temporary (≤ 14 days) left heart support blood pump, indicated for temporary ventricular support for the treatment of ongoing CS that occurs immediately (< 48 hours) following acute MI or open heart surgery or in the setting of cardiomyopathy (including peripartum cardiomyopathy) as a result of isolated left ventricular failure that is not responsive to optimal medical management and conventional treatment. The device is inserted via axillary cutdown or directly into the ascending aorta with SmartAssist.

In 2024, Abiomed recalled 66,390 left-sided Impella devices distributed between 2021 and 2023, including the 2.5, CP, LD, 5.0, and 5.5 models, due to perforation risks of the left ventricle. The recall involved the Instructions for Use and device warnings, which Abiomed has since revised. The FDA identified this as a Class I recall, the most serious type, due to the possibility of serious injury or death (FDA 2024).

COVERAGE POLICY

Left-Sided Devices

A left-sided percutaneous ventricular assist device (pVAD) (e.g., Impella 2.5, Impella CP, Impella CP with SmartAssist, Impella 5.0, Impella 5.5, Impella 5.5 with SmartAssist, Impella LD) may be **considered medically necessary** when ALL the following criteria are met:

1. The requested pVAD is an FDA-approved device intended to be used in accordance with the FDA-label
2. Intended use is for short term (up to 14 days), partial circulatory support
3. Member meets ONE of the following clinical indications:
    a. **Cardiogenic shock (CS)** with ALL the following:
        i. Clinical presentation of hypoperfusion that requires or is refractory to optimal medical and/or mechanical support (e.g., inotropes, vasopressors, intra-aortic balloon pump) as evidenced by ANY of the following:
            1) Systolic blood pressure < 90 mmHg
            2) Mean arterial pressure < 60 or > 30 mmHg below baseline
            3) Cardiac index < 1.8 L/min/m^2 without support or < 2.2 L/min/m^2 with support
            4) Elevated filling pressures (left ventricular end-diastolic pressure > 18 mmHg or right ventricular end-diastolic pressure > 10 mmHg)
        ii. CS is due to isolated ventricular failure in ANY of the following scenarios:
            1) < 48 hours following acute myocardial infarction
            2) < 48 hours following open-heart surgery
            3) Cardiomyopathy (including peripartum cardiomyopathy)
            4) Myocarditis

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b. **High-risk percutaneous coronary intervention (HRPCI)*** with ALL the following:
   i. Member is hemodynamically stable
   ii. Member has severe coronary artery disease
   iii. pVAD is intended for temporary support only (≤ 6 hours) during the HRPCI
   iv. Clinical or anatomical risk of hemodynamic compromise exists (e.g., severe left ventricular dysfunction [ejection fraction < 35%], recent decompensated heart failure, anticipated technically challenging or prolonged intervention, unprotected left main disease, last remaining conduit, or severe multivessel disease)

*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)

Right-Sided Devices

A right-sided pVAD (e.g., Impella RP/RP Flex with SmartAssist) may be **considered medically necessary** when ALL the following criteria are met:

1. The requested pVAD is an FDA-approved device and the intended use is in accordance with the FDA-labeled indications

2. Intended use is for short term (up to 14 days), partial circulatory support

3. Member has a body surface area ≥ 1.5 m^2

4. The pVAD is indicated for acute right heart failure or decompensation within 48 hours of ANY of the following
   a. Left ventricular assist device (LVAD) implantation
   b. Myocardial infarction
   c. Heart transplantation
   d. Open-heart surgery

5. Member is free from ALL the following conditions:
   a. Profound shock
   b. End organ failure
   c. Acute neurologic injury

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

Member should be carefully reviewed for any device-specific contraindications (as applicable):

1. Left-sided devices (e.g., 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 Members 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)
   f. In the setting of cardiogenic shock, ALL the following additional contraindications apply:
      i. Significant right heart failure
      ii. Combined cardiorespiratory failure
      iii. Presence of an Atrial or Ventricular Septal Defect (including post-infarct VSD)

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iv. Left ventricular rupture
v. Cardiac tamponade

2. Right-sided devices (e.g., Impella RP and Impella RP Flex with SmartAssist) are contraindicated for use in Members experiencing ANY of the following conditions:
   a. Disorders of the pulmonary artery wall that would preclude placement or correct positioning of the Impella RP devices
   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

3. Impella devices used in conjunction with intra-aortic balloon pumps are considered **experimental, investigational, and unproven** due to insufficient evidence in the peer-reviewed medical literature to establish long-term safety, efficacy, and effect on net health outcomes.

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 Percutaneous Coronary Intervention (HRPCI)

Systematic Reviews and Meta-Analyses

Sivasubramanian et al. (2025) performed a systematic review and meta-analysis to compare the safety and efficacy of intra-aortic balloon pump (IABP) and left-sided percutaneous ventricular assist devices (pVADs), such as Impella and TandemHeart in patients undergoing HRPCIs without cardiogenic shock. The review included 13 studies, including 1 randomized controlled trial (RCT) (the PROTECT II trial), and 12 cohort studies, for a total of 35,554 patients (30,351 IABP and 5,203 left pVADs). Early mortality (in-hospital or 30-day) was higher among patients receiving IABP compared to those with left pVAD support (odds ratio [OR] 1.53, 95% confidence interval [CI] 1.21-1.94). Additionally, risk of cardiogenic shock was higher with IABP compared to pVAD (OR 2.56, 95% CI 1.98-3.33). No significant differences were observed in terms of complications between groups, including major bleeding, stroke or transient ischemia attack (TIA), acute kidney injury, arrhythmia, or length of hospital stay. Heterogeneity was low for early mortality outcomes (I^2 = 50%) but moderate for cardiogenic shock (I^2 = 69%). Although prior reports have suggested left pVADs have higher bleeding and vascular complication rates, this analysis did not confirm these findings and no major differences in adverse reactions were identified between the two types of devices. Funnel plots indicated publication bias, with small studies showing variable results and asymmetry, suggesting underreporting of studies with neutral or unfavorable left pVAD outcomes. The authors also emphasized that this review differs from earlier meta-analyses by focusing exclusively on non-shock HRPCI, a population in which device choice remains more ambiguous. Despite the observed survival advantage of left PVADs, the authors caution that the evidence is primarily observational and that residual confounding and selection bias is likely. Additionally, pVADs were reported to be substantially more expensive than IABPs (mean index admission costs ($96,700 for pVADs vs. $71,900 for IABP), which limits their cost-effectiveness despite potential improvements in short-term outcomes. The authors concluded that left pVAD in HRPCI was associated with lower early mortality and reduced risk of cardiogenic shock compared to IABP, with no significant difference in bleeding, acute kidney injury, stroke/TIA, arrhythmia, or hospital stay. However, because most included studies were non-randomized and exhibited moderate heterogeneity, these findings should be interpreted cautiously.

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 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 HRPCI were significantly associated with a reduced risk of mortality compared to that

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started after HRPCI (OR 0.49, 95% CI 0.26-0.92, I^2 = 0%, p = 0.03 and OR 0.29, 95% CI 0.14-0.62, I^2 = 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, I^2 = 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-HRPCI group, 19% versus 44.7% in the post-PCI group (HR 0.3, 95% CI 0.09-0.96, p = 0.042).

Elia et al. (2022) completed a systematic review and meta-analysis to examine the clinical use and short-term safety and efficacy outcomes of the Impella device in HRPCI. The analysis included 9 studies (1 RCT and 8 retrospective observational studies) with a total of 7,448 patients. The majority of patients (88.7%) used the Impella 2.5 device, while fewer patients used the Impella CP (10.8%) and Impella 5.0 (0.2%). Key outcomes included in-hospital death (5.09%), vascular complications (2.53%), postprocedural stroke (2.77%), major bleeding (5.98%), and postprocedural dialysis (4.44%). Results indicate that while the Impella device has an acceptable rate of complications in HRPCI, mortality remains significant, and it is unclear which patients benefit most. Strengths of the study include adherence to Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines, a comprehensive search strategy, and independent review. However, limitations include high heterogeneity between studies and a lack of comparators.

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.

Non-Randomized Studies, Retrospective Reviews, and Other Evidence

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.

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Cardiogenic Shock

Randomized Controlled Trials

Møller et al. (2024) conducted an international, multicenter, RCT to evaluate the efficacy and safety of a microaxial flow pump (the Impella CP) plus standard care compared to standard care alone in adults with ST-segment elevation myocardial infarction (STEMI) complicated by cardiogenic shock. A total of 360 participants underwent randomization, and 355 were included in the final analysis (179 in the pVAD with standard care group and 176 in the control group). The primary outcome was death from any cause at 180 days, and secondary outcomes included a second composite cardiac end-point event (escalation of treatment to additional mechanical circulatory support, heart transplantation, or death, whichever occurred first), and days alive and out of the hospital. Death from any cause occurred in 82 of 179 patients (45.8%) in the intervention group and in 103 of 176 patients (58.5%) in the control group (HR 0.74, 95% CI 0.55 to 0.99, p = 0.04). A composite cardiac end-point event occurred in 94 of 179 (52.5%) of patients in the intervention group and in 112 of 176 patients (63.6%) in the control group (HR 0.72, 95% CI, 0.55 to 0.95). The mean number of days alive and out of the hospital was 82 days in the intervention group and 73 in the control group (mean between-group difference 8 days, 95% CI -8 to 25 days). The RCT also included a composite safety end point consisting of adverse events like severe bleeding, limb ischemia, hemolysis, device failure, or worsening aortic regurgitation. A composite safety end-point event occurred in 43 patients (24.0%) in the intervention group and 11 (6.2%) in the control group (RR 4.73, 95% CI 2.36 to 9.55). Renal replacement therapy was administered to 75 patients (41.9%) in the intervention group and to 47 patients (26.7%) in the control group (RR 1.98, 95% CI 1.27 to 3.09). The authors emphasized that the trial was open-label and not blinded, which may have influenced results. The authors concluded that the routine use of a microaxial flow pump with standard care in the treatment of patients with STEMI-related cardiogenic shock led to a lower risk of death from any cause at 180 days when compared to standard care alone. However, it was also associated with a higher incidence of a composite of serious adverse events. (ClinicalTrials.gov NCT01633502).

Systematic Reviews and Meta-Analyses

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 RCTs, 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. 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.

Bhatia et al. (2022) conducted a systematic review and meta-analysis comparing the use of VA-ECMO with or without Impella for left ventricular unloading in patients with cardiogenic shock. Seven observational studies were included in the review, with a total of 1,054 patients. Of these, a total of 391 patients were treated with VA-ECMO with Impella concurrently. The primary outcome was short-term all-cause mortality, which included in-hospital or 30-day mortality. Secondary outcomes included major bleeding, hemolysis, continuous renal replacement therapy, weaning from mechanical circulatory support, limb ischemia, and transition to destination therapy (e.g., left ventricular assist device or cardiac transplant). Overall, short-term mortality was significantly lower in patients supported with VA-ECMO with Impella versus without (risk ratio [RR] 0.89, I^2 = 0%, p = 0.038). Additionally, transition to destination therapy was more likely in patients supported with VA-ECMO with Impella (RR 2.03, I^2 = 0%, p = 0.001). Rates of weaning off all temporary mechanical circulatory support during in-hospital stay did not significantly differ between groups (RR 1.2, I^2 = 0%, p = 0.21). Patients supported with VA-ECMO with Impella had a higher risk of intravascular hemolysis (RR 2.03, I^2 = 0%, p < 0.001), renal failure requiring continuous renal replacement therapy (RR 1.46, I^2 = 11%, p < 0.0001), and limb ischemia (RR 1.67, I^2 = 0%, p = 0.01). Overall, the use of VA-ECMO with Impella was associated with an 11% lower risk of short-term mortality and a higher likelihood of progression to destination therapy; however, it was also

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associated with higher rates of hemolysis, limb ischemia, and renal failure. The authors concluded that prospective, randomized trials are needed to define the optimal treatment strategy in this high-risk cohort.

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.

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%).

Non-Randomized Studies, Retrospective Reviews, and Other Evidence
Karami et al. (2021) conducted a 5-year follow-up of the multicenter, randomized IMPRESS in Severe Shock trial (NTR3450) after initial randomization. All-cause mortality was retrieved from the Dutch population (BRP; in Dutch 'Basisregistratie Personen') register. 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.

Acute Right-Sided Heart Failure
Non-Randomized Studies, Retrospective Reviews, and Other Evidence
Botti et al. (2022) conducted the IMP-IT study, initiated by the Italian Society of Interventional Cardiology (GISE), a retrospective observational national registry that includes data from 17 Italian centers spanning 2004 to June 2018. The use of percutaneous right ventricular assist devices (pRVADs), like the Impella RP, is on the rise for treating patients with right ventricular (RV)-dominant cardiogenic shock (CS) unresponsive to optimal medical treatment. The Impella RP is notable for being the first pRVAD approved by the FDA for this condition. The study examined patients treated with various Impella devices, including Impella 2.5, Impella CP, Impella 5.0, and Impella RP, for both CS and high-risk percutaneous coronary intervention (HR-PCI). This sub-analysis focused on: (1) assessing the characteristics of patients receiving Impella RP support and (2) evaluating in-hospital and one-year clinical outcomes for these patients. The main clinical endpoint was a composite of death, heart failure rehospitalization, left ventricular assist device (LVAD) implantation, or heart transplantation. Fifteen patients treated with Impella RP were included in this analysis. Sixty percent of these patients received Impella RP alone, while the rest required biventricular support with combinations of Impella RP and Impella 2.5 or Impella CP. Nearly half of the patients also needed additional

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mechanical support with an intra-aortic balloon pump (IABP). The study found in-hospital mortality at 46.7% and one-year mortality at 53.3%. At one year, the composite rate of all-cause death, heart failure hospitalization, LVAD implantation, and heart transplantation was 60%. While the Impella RP shows favorable survival outcomes in RV-predominant cardiogenic shock, it is associated with frequent device-related complications, warranting careful consideration when initiating its use. Currently, no randomized controlled trials have been conducted for Impella RP, and the available registry data is limited to the RECOVER RIGHT registry, which includes 30 patients treated with Impella RP. These findings underscore the need for prospective studies to develop guidelines for the timing and escalation of Impella RP usage.

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

In a joint initiative by the **International Society for Heart and Lung Transplantation (ISHLT) and the Heart Failure Society of America (HFSA)**, Bernhardt et al. (2023) published guidelines for the management of patients needing acute mechanical circulatory support (MCS). These guidelines point out that indications for acute MCS in those with cardiogenic shock can differ due to the diverse causes and severity of the condition. They also highlight that the expected outcomes of the support, such as recovery, decision-making bridges, and duration of support, can influence these indications. The key recommendations with levels of evidence include, but are not limited to:

- "Acute MCS should be initiated as soon as possible in patients with cardiogenic shock who fail to stabilize or continue to deteriorate despite initial interventions. Class I recommendation – strong; Level of evidence B - moderate quality.
- The use of acute MCS should be considered in patients with multiorgan failure to allow successful optimization of clinical status and neurologic assessment before placement of durable MCS or organ transplantation. Class II recommendation - moderate; Level of evidence – C."

The **American Association for Thoracic Surgery (AATS)** and the **ISHLT** published guidelines on selected topics in mechanical circulatory support, including recommendations on the use of pVADs. The guidelines note that compared with IABP, contemporary pVADs "provide a significant increase in cardiac index and mean arterial pressure; however, reported 30-day outcomes are similar." The type of pVADs that provide the most flow typically have larger catheter sizes, which carry higher risk for vascular compromise and limit ambulation. While some newer pVADs enter through the axillary or subclavian artery to increase mobility, this comes at a cost by being a more invasive procedure. While pVADs can be useful, attempts at hemodynamic optimization should not delay the implantation of a durable mechanical circulatory support device. "Often 1 to 3 days is sufficient, and if improvements are not seen despite escalation of therapy, then surgically placed temporary support may be needed or the patient's appropriateness for permanent support should be reconsidered" (Kirklin et al. 2020).

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The **Society for Cardiovascular Angiography and Interventions (SCAI), American College of Cardiology (ACC), HFSA,** and **Society for Thoracic Surgeons (STS)** published a 2015 *expert consensus statement on the use of percutaneous mechanical circulatory support devices in cardiovascular care*, such as IABPs, left atrial-to-aorta assist devices (e.g., TandemHeart), and left ventricle-to-aorta assist devices (e.g., Impella), ECMO, and methods of right-sided support. The consensus was endorsed by the **American Heart Association (AHA)**. The authors state that while a 2011 guideline by the ACC, AHA, and SCAI recommend consideration of pVADs as an adjunct to HRPCI and for CS in patients presenting with STEMI, no additional guidance is provided. Therefore, the purpose of the consensus statement is to provide additional guidance on the appropriate clinical settings for pVAD utilization and related information (Rihal et al. 2015).

One of the suggested indications for pVAD use 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 authors highlight that every aspect of a percutaneous coronary intervention carries potential risk to the coronary vasculature. While no single definition for HRPCI exists, certain variables elevate this risk and can be categorized into three major groups: patient specific (e.g., age, impaired left ventricular function, chronic kidney disease, diabetes mellitus, etc.), lesion specific (e.g., anatomical characteristics such as left main stenosis and bifurcation disease), and clinical presentation specific (e.g., clinical scenarios that can increase the risk of an adverse event, such as CS or acute coronary syndrome). Overall, the need for a mechanical circulatory device for HRPCI depends on the hemodynamic condition of the patient, the anticipated risk of hemodynamic compromise during the procedure, and the need for hemodynamic support following revascularization (Rihal et al. 2015).

The authors also discuss new, emerging applications for pVAD technology, such as non-operable valvular disease and electrophysiologic procedures. Carefully selected patients may benefit from cardiac support during percutaneous valvuloplasty or aortic valve replacement. Additionally, patients with severe left ventricular dysfunction may not tolerate sustained arrhythmias during prolonged electrophysiological mapping and ablation procedures (Rihal et al. 2015).

Finally, the authors emphasize that definitive clinical evidence for the use of percutaneous MCS devices are in many cases unavailable or controversial. As a result, they provide consensus-based statements bases on “the anticipated hemodynamic effects and risks,” which includes the following:

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 CS 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.

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10. Registries and randomized controlled trials comparing different strategies in different clinical scenarios are critically needed."

The 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)

Code	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

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APPROVAL HISTORY

12/10/2025	Policy revised. Moved STEMI to fall under Cardiogenic Shock instead of a standalone indication. Revised CS, HRPCI, and Impella RP/RP Flex criteria. Removed electrophysiologic procedures from clinical indications and E/I/U statement regarding concurrent use with ECMO. Organized coverage policy into left and right-sided devices for clarity. IRO peer reviewed on December 2, 2025 by a practicing physician board certified in cardiovascular disease.
12/11/2024	Policy reviewed. No changes to coverage criteria. Updated Summary of Medical Evidence and References.
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

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	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.

REFERENCES

1. Abiomed. Important safety information: Impella left-sided devices indication & safety information. Published 2025. Accessed November 12, 2025. https://www.abiomed.com/en-us/important-safety-information
2. 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. PMID: 26681124.
3. Ardito V, Sarucanian L, Rognoni C, et al. Impella versus VA-ECMO for patients with cardiogenic shock: Comprehensive systematic literature review and meta-Analyses. J Cardiovasc Dev Dis. 2023 Apr 5;10(4):158. doi: 10.3390/jcdd10040158. PMID: 37103037; PMCID: PMC10142129.
4. Batchelor RJ, Wheelahan A, Zheng WC, et al. Impella versus venoarterial extracorporeal membrane oxygenation for acute myocardial infarction cardiogenic shock: A systematic review and meta-analysis. J Clin Med. 2022 Jul 7;11(14):3955. doi: 10.3390/jcm11143955. PMID: 35887718; PMCID: PMC9317942.
5. 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.
6. Bernhardt AM, Copeland H, Deswal A, et al. Task Force 1; Task Force 2; Task Force 3; Task Force 4. The International Society for Heart and Lung Transplantation/Heart Failure Society of America guideline on acute mechanical circulatory support. J Card Fail. 2023 Mar;29(3):304-374. doi: 10.1016/j.cardfail.2022.11.003. Epub 2023 Feb 6. Erratum in: J Card Fail. 2024 Jan;30(1):119. doi: 10.1016/j.cardfail.2023.10.005. PMID: 36754750.
7. Bhatia K, Jain V, Hendrickson MJ, Aggarwal D, Aguilar-Gallardo JS, Lopez PD, et al. Meta-Analysis Comparing Venoarterial Extracorporeal Membrane Oxygenation With or Without Impella in Patients With Cardiogenic Shock. Am J Cardiol. 2022 Oct 15;181:94-101. doi: 10.1016/j.amjcard.2022.06.059. Epub 2022 Aug 21. PMID: 35999070.
8. Bochaton T, Huot L, Elbaz M, et al. IMPELLA-STIC investigators. Mechanical circulatory support with the Impella® LP5.0 pump and an intra-aortic balloon pump for cardiogenic shock in acute myocardial infarction: The IMPELLA-STIC randomized study. Arch Cardiovasc Dis. 2020 Apr;113(4):237-243. doi: 10.1016/j.acvd.2019.10.005. PMID: 31740272.
9. Botti G, Gramegna M, Burzotta F, IMP IT Investigators et al. Impella RP for patients with acute right ventricular failure and cardiogenic shock: A subanalysis from the IMP-IT registry. J Pers Med. 2022 Sep 9;12(9):1481. doi: 10.3390/jpm12091481. PMID: 36143266; PMCID: PMC9506315.
10. Cappannoli L, Galli M, Zito A, et al. Venoarterial extracorporeal membrane oxygenation (VA-ECMO) with vs. without left ventricular unloading by Impella: A systematic review and meta-analysis. Eur Heart J Qual Care Clin Outcomes. 2023 Jun 21;9(4):358-366. doi: 10.1093/ehjqcco/qcac076. PMID: 36370449.
11. Del Rio-Pertuz G, Benjanuwattra J, Juarez M, et al. Efficacy of mechanical circulatory support used before versus after primary percutaneous coronary intervention in patients with cardiogenic shock from ST-elevation myocardial infarction: A systematic review and meta-analysis. Cardiovasc Revasc Med. 2022 Sep; 42:74-83. doi: 10.1016/j.carrev.2022.05.002. PMID: 35570152.
12. Elia E, Iannaccone M, D'Ascenzo F, et al. Short term outcomes of Impella circulatory support for high-risk percutaneous coronary intervention a systematic review and meta-analysis. Catheter Cardiovasc Interv. 2022 Jan 1;99(1):27-36. doi: 10.1002/ccd.29757. Epub 2021 May 24. PMID: 34028964.
13. Jeevanandam V, Eisen HJ. Short-term mechanical circulatory assist devices. Updated October 14, 2024. Literature review current through October 2025. Accessed November 6, 2025. https://uptodate.com/
14. Hemradj VV, Karami M, Sjauw KD, et al. Pre-PCI versus immediate post-PCI Impella initiation in acute myocardial infarction complicated by cardiogenic shock. PLoS One. 2020 Jul 20;15(7): e0235762. doi: 10.1371/journal.pone.0235762. PMID: 32687502; PMCID: PMC7371192.
15. 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. PMID: 28941078.
16. Karami M, Eriksen E, Ouweneel DM, et al. Long-term 5-year outcome of the randomized IMPRESS in severe shock trial: Percutaneous mechanical circulatory support vs. intra-aortic balloon pump in cardiogenic shock after acute myocardial infarction. Eur Heart J Acute Cardiovasc Care. 2021 Dec 6;10(9):1009-1015. doi: 10.1093/ehjacc/zuab060. PMID: 34327527; PMCID: PMC8648392.
17. Kirklin JK, Pagani FD, Goldstein DJ, et al. American Association for Thoracic Surgery/International Society for Heart and Lung Transplantation guidelines on selected topics in mechanical circulatory support. J Thorac Cardiovasc Surg. 2020 Mar;159(3):865-896. doi: 10.1016/j.jtcvs.2019.12.021. PMID: 31983522.
18. Møller JE, Engstrøm T, Jensen LO, Eiskjær H, Mangner N, Polzin A, et al. Microaxial Flow Pump or Standard Care in Infarct-Related Cardiogenic Shock. N Engl J Med. 2024 Apr 18;390(15):1382-1393. doi: 10.1056/NEJMoa2312572. Epub 2024 Apr 7. PMID: 38587239.
19. Munoz Tello C, Jamil D, Tran HH, et al. The therapeutic use of Impella device in cardiogenic shock: A systematic review. Cureus. 2022 Oct 7;14(10): e30045. doi: 10.7759/cureus.30045. PMID: 36381689; PMCID: PMC9637443.
20. National Institute for Health and Clinical Excellence (NICE). Percutaneous insertion of a temporary heart pump for left ventricular

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haemodynamic support in high-risk percutaneous coronary interventions. Interventional procedures guidance [IPG633]. Published November 28, 2018. Accessed November 22, 2024. https://www.nice.org.uk/guidance
21. National Institute for Health and Clinical Excellence (NICE). Impella 2.5 for hemodynamic support during high-risk percutaneous coronary interventions. Medtech innovation briefing [MIB89]. Published November 29, 2016. Accessed November 22, 2024. https://www.nice.org.uk/guidance
22. 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.
23. Panuccio G, Neri G, Macrì LM, et al. Use of Impella device in cardiogenic shock and its clinical outcomes: A systematic review and meta-analysis. Int J Cardiol Heart Vasc. 2022 Mar 25; 40:101007. doi: 10.1016/j.ijcha.2022.101007. PMID: 35360892; PMCID: PMC8961185.
24. Rihal CS, Naidu SS, Givertz MM, Szeto WY, Burke JA, Kapur NK 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 American Heart Assocation, the Cardiological Society of India, and Sociedad Latino Americana de Cardiologia Intervencion; Affirmation of Value by the Canadian Association of Interventional Cardiology-Association Canadienne de Cardiologie d'intervention. J Am Coll Cardiol. 2015 May 19;65(19):e7-e26. doi: 10.1016/j.jacc.2015.03.036. Epub 2015 Apr 7. PMID: 25861963.
25. Sivasubramanian D, Senthilkumar V, Nanda Palanisamy N, Bilgaiyan R, Aravind S, Kumar SD, et al. Comparative Outcomes of Intra-Aortic Balloon Pump Versus Percutaneous Left Ventricular Assist Device in High-Risk Percutaneous Coronary Intervention: A Systematic Review and Meta-Analysis. J Clin Med. 2025 Aug 1;14(15):5430. doi: 10.3390/jcm14155430. PMID: 40807051; PMCID: PMC12347093.
26. United States (Food and Drug Administration (FDA). Abiomed recalls the instructions for use for Impella left sided blood pumps due to perforation risks. Published December 27, 2023. Updated March 21, 2024. Accessed November 12, 2025. https://www.fda.gov
27. United States Food and Drug Administration (FDA). Pre-market approval (PMA): IMPELLA 2.5 system. Product code OZD. PMA: P140003. Accessed November 12, 2025. https://www.fda.gov
28. United States Food and Drug Administration (FDA). Pre-market approval (PMA): Impella 5.0. Product code OZD. PMA: P140003 S049. Accessed November 12, 2025. https://www.fda.gov
29. United States Food and Drug Administration (FDA). Pre-market approval (PMA): IMPELLA CP SYSTEM. Product code OZD. PMA: P140003 S011. Accessed November 12, 2025. https://www.fda.gov
30. United States Food and Drug Administration (FDA). Pre-market approval (PMA): IMPELLA LEFT VENTRICULAR SUPPORT SYSTEM. Product code OZD. PMA: P140003 S005. Accessed November 12, 2025. https://www.fda.gov
31. United States Food and Drug Administration (FDA). Pre-market approval (PMA): Impella RP Flex with SmartAssist. Product code PYX. PMA: P170011 S039. Accessed November 12, 2025. https://www.fda.gov
32. United States Food and Drug Administration (FDA). Pre-market approval (PMA): Impella RP System (multiple approvals). Product code PYX. PMA: P170011. Accessed November 12, 2025. https://www.fda.gov

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