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DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (i.e., will be paid for by Molina) for a particular member. The member's benefit plan determines coverage. Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this Molina Clinical Policy (MCP) document and provide the directive for all Medicare members.[1 2]

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL [2-5]

Percutaneous ventricular assist devices (pVADs) have been developed for short-term use (4-6 hours) in patients who require acute circulatory support. These devices are intended for individuals requiring partial circulatory

support using an extracorporeal; bypass control unit during procedures not requiring cardiopulmonary bypass. These devices are placed through the femoral artery or vein. Two different pVADs have been developed, the TandemHeart™ (Cardiac Assist™, Pittsburgh, PA), and the Impella® device (Abiomed, Inc., Danvers, MA). In the TandemHeart™ system, a catheter is introduced through the femoral vein and passed into the left atrium via transseptal puncture. Oxygenated blood is then pumped from the left atrium into the arterial system via the femoral artery. The Impella device is introduced through a femoral artery catheter. In this device, a small pump is contained within the catheter that is placed into the left ventricle. Blood is pumped from the left ventricle, through the device, and into the ascending aorta. Adverse events associated with pVAD include access site complications such as bleeding, aneurysms, or leg ischemia. Cardiovascular complications can also occur, such as perforation, myocardial infarction (MI), stroke, and arrhythmias.

Food and Drug Administration (FDA): The following devices have received FDA approvals:

- Impella® Recover LP 2.5 Percutaneous Cardiac Support System (Abiomed, Inc., Danvers, MA)
- Impella 2.5 Plus/Impella CP (Abiomed, Inc., Danvers, MA)
- Impella 5.0 Catheters (Abiomed, Inc., Danvers, MA)
- Impella RP System (Abiomed, Inc., Danvers, MA)
- Impella 5.5 with SmartAssist (Abiomed, Inc., Danvers, MA)
- TandemHeart® (Cardiac Assist, Pittsburgh)

CLINICAL CRITERIA [1-5]

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

- ❑ The pVAD must be an FDA approved device and used according to their FDA labeled indications; and
- ❑ For partial circulatory support short term use (up to 4-6 hours) for any of the following clinical indications: [ONE]
  - ST segment elevation myocardial infarction (STEMI) when unable to be stabilized with pharmacological therapy
  - Refractory cardiogenic shock
  - As an adjunct to Percutaneous Coronary Intervention (PCI) in carefully selected high-risk patients: [ONE]
    - ➢ undergoing unprotected left main or last-remaining patent conduit PCI;
    - ➢ severely depressed ejection fraction (≤ 35%) undergoing PCI of a vessel supplying a large territory;
    - ➢ three vessel disease with ejection fraction ≤ 30%;
    - ➢ presence of cardiogenic shock

CONTINUATION OF THERAPY [1-5]

The Percutaneous Ventricular Assist Devices (pVAD) may only be used short term (for up to 4-6 hours).

LIMITATIONS [1-5 51]

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

- **Impella Devices:** Mechanical aortic valve or left ventricular thrombus, ventricular septal defect, and severe peripheral arterial disease that may prevent cannula insertion
  - relative contraindications include aortic stenosis and regurgitation
- **TandemHeart:** Ventricular septal defects, right ventricular failure, right or left atrial thrombosis, aortic insufficiency, aortic dissection, coagulopathies and bleeding disorders, and severe peripheral arterial disease that may prevent cannula insertion

SUMMARY OF MEDICAL EVIDENCE [6-48]

The published evidence consists of randomized controlled trials, clinical trials, meta-analysis, systematic reviews, and retrospective studies that evaluated the efficacy and safety of percutaneous ventricular support devices (pVAD) for the management of cardiogenic shock, as an adjunct to percutaneous coronary intervention (PCI), unstable patients with ST segment elevation myocardial infarction and in other complex cardiovascular procedures. Most RCTs compared pVAD to intra-aortic balloon pumps (IABP). Complications have been reported when using pVADs with high risk PCI procedures, but several studies have shown that the major adverse event rate at 30 and 90+ days post pVADs are favorable. Studies of patients with cardiogenic shock refractory to IABP have reported improved hemodynamic parameters following pVAD placement.

A summary of the most relevant and current literature is provided below.

Percutaneous Coronary Intervention

For PCI, the majority of the evidence is derived from the PROTECT II study (O'Neill et al., 2012), which was a randomized controlled trial (RCT) comparing the Impella 2.5 with an IABP. In this study, 452 symptomatic patients with complex 3-vessel disease or unprotected left main coronary artery disease and severely depressed left ventricular function were randomly assigned to intra-aortic balloon pump (IABP) (n=226) or Impella 2.5 (n=226) support during non-emergent high-risk percutaneous coronary intervention. Improved outcomes were observed for Impella 2.5-supported patients at 90 day follow-up. [25]

Kovacic et al. (2015) evaluated the efficacy of Impella 2.5 compared with IABP in a subgroup analysis of the PROTECT II study in 325 patients with 3-vessel CAD and LVEF 30%. Results of this preplanned subgroup suggest that use of Impella 2.5 compared with IABP seems to reduce the composite incidence of major adverse events at 90 days, but not at 30 days. [19]

A more recent meta-analysis and conducted by Rios et al. (2018) compared the benefits and harms of intra-aortic balloon pump (IABP) versus percutaneous ventricular assist devices (pVAD) (TandemHeart and the Impella 2.5, CP or 5.0) during high-risk percutaneous coronary intervention (PCI) or cardiogenic shock (CS). Five randomized controlled trials were included (Thiele, et al., 2005 [n=20]; Burkhoff, et al., 2006 [n=35]; Seyfarth, et al., 2008 [n=32]; O'Neill, et al., 2012 [n=236]; Ouweneel, et al., 2017 [n=48]) and one

nonrandomized study comparing pVAD versus IABP. Based on the RCTs, there was no difference in short-term (six months) (p=0.59) or long-term (12 months) (p=1.00) all-cause mortality. [44]

Another recent systematic review of randomized controlled trials (RCTs) and observational studies by Ait Ichou et al. (2018) was conducted to synthesize the currently 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 four RCTs [Seyfarth, et al., 2008; O'Neil, et al., 2012; Ouweneel, et al., 2016, 2017] and 16 observational studies, including a total of 1287 patients. All studies were published between 2006 and 2016, and the durations of follow-up ranged from 1-42 months. Ten studies examined prophylactic use of the Impella device among high-risk patients undergoing elective PCI, five examined its use among high-risk patients undergoing emergent PCI, and four examined its use in mixed populations of high-risk patients undergoing elective or emergent PCI. Mean LVEF was low, ranging from 23%-37%, while the percentage of patients with previous MI was variable, ranging from 24%-76%. Overall, patients had multiple comorbidities and were at high procedural risk. The use of Impella resulted in improved procedural and hemodynamic characteristics in controlled and uncontrolled studies. In controlled studies, the 30-day rates of all-cause mortality and major adverse cardiac events (MACE) were similar across groups. In most uncontrolled studies, the 30-day rates of all-cause mortality were generally low (range: 3.7%–10%), though rates of MACE were slightly higher (range: 5%–20%). The authors concluded that there is limited evidence available concerning the effect of Impella on clinical events, particularly compared to IABP, although procedural and hemodynamic results appear promising. [38]

Cardiogenic Shock

For 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 (CS). The primary outcome was survival to discharge. This meta-analysis included six 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 postcardiotomy cardiogenic shock, 27 (16.6%) for acute myocardial infarction 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 postcardiotomy 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%). [39]

A randomized, prospective, open-label, multicenter study by Ouweneel et al. (2017) was conducted to determine whether a new percutaneous mechanical circulatory support (pMCS) device (Impella CP) decreases 30-day mortality when compared with an intra-aortic balloon pump (IABP) in patients with severe shock complicating AMI. A total of 48 patients with severe cardiogenic shock (CS) complicating AMI were assigned to pMCS (n=24) or IABP (n=24). Severe CS was defined as systolic blood pressure <90 mm Hg or the need for inotropic or vasoactive medication and the requirement for mechanical ventilation. The primary endpoint was 30-day all-cause mortality. At 30 days, mortality in patients treated with either IABP or pMCS was similar (50% and 46%, respectively). At six months, mortality rates for both pMCS and IABP were 50%. [43]

A meta-analysis of randomized trials by Thiele et al. (2017) investigated the efficacy and safety of percutaneous active mechanical support system (MCS) vs. control [intra-aortic balloon pumping (IABP)] in cardiogenic shock (CS). The primary endpoint of 30-day mortality and device-related complications including bleeding and leg ischemia were analyzed. Four trials randomizing 148 patients to either TandemHeart or Impella MCS (n=77) vs. control (n=71) were identified. Two trials used the TandemHeart device (Thiele et al. 2005; Burkhoff et al. 2006) and two trials used the Impella device [Impella 2.5 (Seyfarth, et al., 2008) and Impella CP (Ouweneel, et al., 2017)]. There was no difference in 30-day mortality. The authors recommend that the use of active percutaneous MCS may thus be restricted to selected patients. [48]

PROFESSIONAL SOCIETY GUIDELINES [49-53]

The 2015 Society for Cardiovascular Angiography and Interventions / American College of Cardiology / Heart Failure Society of America / Society for Thoracic Surgeons (SCAI/ACC/HFSA/STS) consensus statement on the use of percutaneous mechanical circulatory support (MCS) states that percutaneous MCS, particularly with the Impella and TandemHeart, is superior to pharmacologic therapy for providing hemodynamic support and these devices should be available and reimbursed (Rihal et al., 2015). One of the suggested indications for percutaneous MCS is for patients undergoing high-risk PCI, especially if the patient is inoperable or has a low LVEF (< 20% to 30%) and complex CAD involving a large territory (i.e., sole remaining vessel, left main disease, or 3-vessel disease). [51]

CODING INFORMATION: THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

CPT	Description
33990	Insertion of ventricular assist device, percutaneous including radiological supervision and interpretation; arterial access only
33991	Insertion of ventricular assist device, percutaneous including radiological supervision and interpretation; both arterial and venous access, with transseptal puncture
33992	Removal of percutaneous ventricular assist device at separate and distinct session from insertion
33993	Repositioning of percutaneous ventricular assist device with imaging guidance at separate and distinct session from insertion

HCPCS	Description
	N/A

ICD-9	Description: [For dates of service prior to 10/01/2015]
37.68	Insertion of percutaneous external heart assist device
410.00-411.89	Acute myocardial infarction and other acute and subacute forms of ischemic heart disease
414.00-414.07	Coronary atherosclerosis
428.0- 428.9	Heart failure
785.51	Cardiogenic shock

ICD-10	Description: [For dates of service on or after 10/01/2015]
I20-I25.9	Ischemic Heart Disease
I50-I50.9	Heart Failure
R57.0	Cardiogenic shock

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    - Impella CP (Abiomed) For Use In Adult Patients With Cardiogenic Shock. Aug, 2017. Updated Aug, 2018. [archived Sept, 2020]
    - Impella 5.5 (Abiomed, Inc.) for the Temporary Treatment of Cardiogenic Shock. Oct, 2020.
55. UpToDate: [website]: Waltham, MA: Walters Kluwer Health; 2019.
    - Aroesty JM, Jeevanandam V, Eisen HJ. Short-term mechanical circulatory assist devices.
56. Advanced Medical Review (AMR): Policy reviewed by practicing MD board certified in Internal Medicine, Cardiovascular Disease. 7/17/19.

REVISION/REVIEW HISTORY:

2/27/13: New Policy
12/16/15: Policy reviewed and there have been no changes to the criteria.
7/27/16: Policy was reviewed and updated. No changes were made to the criteria. Summary of medical evidence and reference sections were updated.
6/22/17 & 3/8/18: Policy reviewed and there have been no changes to the criteria.
12/10/19: Policy reviewed, no changes to criteria. Updated the contraindication section based on FDA information. Updated references, guidelines, coding tables. Revised and condensed the section on summary of medical evidence based on new literature. Revised FDA information based on new devices approved.
12/9/20: Policy reviewed, no changes to criteria. Added one additional FDA approval for the Impella 5.5 SmartAssist.