# Impeller Driven Percutaneous Ventricular Assist Devices (Trade Name Impella)

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| Policy Number: | **M20180912076** |
| Effective Date: | **11/1/2018** |
| Sponsoring Department: | **Health Care Services** |
| Impacted Department(s): | **Health Care Services** |

**Type of Policy:** ☒ Internal ☒ External

**Data Classification:** ☐Confidential ☐Restricted ☒Public

## Applies to (Line of Business):

☐ Corporate (All)
☒ State Products, if yes which plan(s): ☒MediSource; ☒ MediSource Connect; ☒Child Health Plus ☒Essential Plan
☒ Medicare, if yes, which plan(s): ☒MAPD; ☐PDP; ☒ISNP; ☒CSNP
☒ Commercial, if yes, which type: ☒Large Group; ☒Small Group; ☒Individual
☒ Self-Funded Services *(Refer to specific Summary Plan Descriptions (SPDs) to determine any pre-authorization or pre-certification requirements and coverage limitations. In the event of any conflict between this policy and the SPD of a Self-Funded Plan, the SPD shall supersede the policy.)*

## Excluded Products within the Selected Lines of Business (LOB)

N/A

## Applicable to Vendors? Yes ☐ No☒

## Purpose and Applicability:

To set forth Independent Health's medical necessity criteria for the use of **impeller driven percutaneous ventricular assist devices (idpVAD)**.

## Policy:

**Commercial, Self-Funded, Medicare Advantage, MediSource, MediSource Connect, Child Health Plus and Essential Plan:**

Independent Health considers the use of an Impeller Driven Percutaneous Ventricular Assist Device (idpVAD) (e.g., **Impella 2.5**, Impella 5.0, Impella CP, TandemHeart) medically necessary for the following indications:

- For the acute treatment of cardiogenic shock;
- As an adjunct **to percutaneous coronary intervention (PCI)** in high-risk patients with unprotected left main or last-remaining-conduit PCI with LVEF < 35%, or with 3-vessel disease and LVEF < 30%. The following is required:
    - Member has been evaluated utilizing the New York State PCI risk scoring system; AND
    - Documentation of a second interventional cardiologist opinion which states agreement with the appropriateness of the procedure for this patient; AND
    - Documentation of a cardiothoracic surgical opinion as to the suitability of the patient for a percutaneous intervention and the acute risk of the percutaneous intervention and stating patient is not a candidate for operative intervention.

**Background:**

Temporary mechanical circulatory support (MCS) refers to a group of devices generally used for less than 30 days to maintain adequate organ perfusion by compensating for a failure of the pumping mechanism of the heart. Examples of temporary MCS devices include the **Intraaortic balloon pump (IABP)**, veno-arterial-extracorporeal membrane oxygenation (VA-ECMO), impeller driven percutaneous ventricular assist devices (Tandem Heart and the Impella device). Percutaneous ventricular assist devices (pVADs) are utilized for short-term bridge to recovery.

On March 23, 2015, the FDA issued a Premarket Approval (PMA) to Abiomed for the Impella 2.5 percutaneous ventricular assist device and on April 7, 2016, Abiomed received additional PMA stating the Impella 2.5, Impella CP, Impella 5.0, and Impella LD Catheters. On September 20, 2017, the FDA issued a further PMA for the Impella RP System.

The Impella system is a miniaturized, continuous flow, axial pump contained within a single pigtail catheter. It is intended to increase cardiac output and coronary perfusion, improve mean arterial pressure, and reduces myocardial oxygen consumption and pulmonary capillary wedge pressure. Using fluoroscopic guidance, the Impella 2.5 catheter is inserted into the femoral artery through a small skin incision and placed across the aortic valve. Insertion of the Impella 2.5 is conducted in a catheterization laboratory or in an operating room by an interventional cardiologist or a cardiothoracic surgeon.

An evaluation of the peer-reviewed scientific literature, including but not limited to subscription materials, has provided Independent Health the basis for its medical necessity coverage outlined above.

## Pre-Authorization Required? Yes ☐ No☐ Other ☒

Pre-authorization is not required at the present time for the indication of cardiogenic shock. Criteria above will be utilized upon retro-review.

Preauthorization is required for the indication of percutaneous coronary intervention.

## Definitions

**Cardiogenic shock (CS**) is defined by systemic hypoperfusion with systolic blood pressure <80 mmHg in the setting of marked decrease in cardiac index (<1.8 L/mm/m2) for greater than or equal to 30 minutes despite adequate intravascular volume with depressed cardiac index (less than or equal to 2.2 liters per minute per square meter of body surface area) and an elevated pulmonary-capillary wedge pressure greater than 15 mm Hg.

**Impeller driven percutaneous ventricular assist device (idpVAD)** is a device which is a miniature impeller pump located within a catheter revolving at high speeds drawing blood out of the left ventricle and ejects it proximally into the ascending aorta.

**Impella 2.5** is an intravascular, nonpulsatile axial blood pump indicated for use during HRPCI. It is inserted percutaneously, usually through the femoral artery, and threaded into the left ventricle, where it pumps blood into the aorta.

**Intraaortic balloon pump (IABP)** is a type of mechanical hemodynamic support utilizing a flexible catheter with one lumen that allows for either distal aspiration/flushing or pressure monitoring and a second that permits the periodic delivery and removal of helium gas to a closed balloon. Indications for IABP include, but are not limited to, cardiogenic shock (left ventricular failure or mechanical complications of an acute myocardial infarction), intractable angina, and low cardiac output after cardiopulmonary bypass.

**Percutaneous coronary intervention (PCI)** also known as coronary angioplasty, is a nonsurgical technique for treating obstructive coronary artery disease, including unstable angina, acute myocardial infarction (MI), and multivessel coronary artery disease (CAD).

**Percutaneous ventricular assist device (pVAD)** is a ventricular assist device which is implanted percutaneously, providing circulatory support in conditions characterized by profoundly reduced ventricular function.

## References

**Related Policies, Processes and Other Documents**
Experimental and Investigation Policy (Policy Number M20150623055).

**Non-Regulatory references**
DiSciascio G, Cowley MJ, Vetrovec GW, Kelly KM, Lewis SA. Triple vessel coronary angioplasty: acute outcome and long-term results. J Am Coll Cardiol. 1988 Jul;12(1):42-8.

Hannan EL, Farrell LS, Walford G, et al. The New York State risk score for predicting in-hospital/30-day mortality following percutaneous coronary intervention. JACC Cardiovasc Interv. 2013 Jun;6(6):614-22.

Hayes, Inc. Annual Review. Impella 2.5 System (Abiomed Inc.) for Cardiac Support in Patients Undergoing High-Risk Percutaneous Coronary Intervention (PCI). Lansdale PA; October 25, 2018.

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Hayes, Inc. Health Technology Brief. Impella 2.5 System (Abiomed Inc.) for Emergent Hemodynamic Support in Patients with Cardiogenic Shock). Lansdale PA; September 2015.

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Health Quality Ontario (web site). Ontario Health Technology Assessment Series Percutaneous Ventricular Assist Devices: A Health Technology Assessment. February 2017 Vol. 17, No.2 Available at: http://www.hqontario.ca/Portals/0/Documents/evidence/reports/hta-impella-1701-en.pdf Accessed October 11, 2023.

Jeevanandam V, Eisen HJ, Pinto DS. Short-term mechanical circulatory assist devices. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. (Accessed on October 10, 2023.)

Medscape. [web site]. Percutaneous Coronary Intervention (PCI). Updated November 27, 2019. Available at: https://emedicine.medscape.com/article/161446-overview. Accessed October 11, 2023.

Reyentovich A, Theile H Prognosis and treatment of cardiogenic shock complicating acute myocardial infarction. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. (Accessed on October 11, 2023.)

Rihal CS, Naidu SS, Givertz MM, et al. 2015 SCAI/ACC/HFSA/STS clinical expert consensus statement on the use of percutaneous mechanical circulatory support devices in cardiovascular care: endorsed by the American Heart Association, 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;65(19):e7-e26.

Saffarzadeh A, Bonde P. Options for temporary mechanical circulatory support. J Thorac Dis. 2015 Dec;7(12):2102-11.

United States Food and Drug Administration (FDA) [web site]. Impella Left Ventricular Support System. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P140003S005 . Accessed October 11, 2023.

United States Food and Drug Administration (FDA) [web site]. Impella RP PMA. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P170011 Accessed October 11, 2023.

**Regulatory References**

New York State Department of Health [web site]. New York State Medicaid Program Physician Procedure Codes. Section 5 – Surgery. April 2023. Available at: https://www.emedny.org/ProviderManuals/Physician/PDFS/Physician%20Procedure%20Codes%20Sect5.pdf Accessed October 11, 2023.

***This policy contains medical necessity criteria that apply for this service. Please note that payment for covered services is subject to eligibility criteria, contract exclusions and the limitations noted in the member's contract at the time the services are rendered.***

## Version Control

Signature / Approval on File? Yes ☒ No☐

| Revision Date | Owner | Notes |
|---|---|---|
| 12/1/2023 | Health Care Services | Revised |
| 12/1/2022 | Health Care Services | Reviewed |
| 12/1/2021 | Health Care Services | Revised |
| 9/1/2021 | Health Care Services | Revised |
| 7/1/2020 | Health Care Services | Reviewed |
| 8/1/2019 | Medical Management | Revised |
| 5/15/2019 | Medical Management | Revised |