Percutaneous Ventricular Assist Devices - Single Service

Clinical Guidelines for Medical Necessity Review

Version: 1.0
Effective Date: December 29, 2023

Important Notices

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Guideline Information:

Specialty Area: Cardiovascular Disease
Guideline Name: Percutaneous Ventricular Assist Devices (Single Service)

Literature review current through: 12/29/2023
Document last updated: 12/29/2023
Type: [**X**] Adult (18+ yo) | [**X**] Pediatric (0-17yo)

Table of Contents

Medical Necessity Criteria

Service: Percutaneous Ventricular Assist Devices

General Guidelines

- **Units, Frequency, & Duration:** None.
- **Criteria for Subsequent Requests:** None.
- **Recommended Clinical Approach:** Mechanical circulatory support (MCS) may be appropriate for patients with advanced heart failure with reduced ejection fraction (HFrEF). Technology has progressed to allow MCS to be used in a variety of clinical situations involving critically ill patients or high-risk procedures.[1] MCS is characterized in a variety of ways, including the expected use length (i.e., short-term (temporary, non-implanted, usually placed percutaneously), intermediate to long-term (destination, implanted)), ventricle assisted (left, right, both), and the physical location of the pumping device (intracorporeal vs extracorporeal). Short-term devices include the intra-aortic balloon pump (IABP), other percutaneous devices (Impella or TandemHeart), extracorporeal mechanical oxygenation (ECMO), and centrifugal pumps used for coronary artery bypass surgery (CABG).[2-3] Contraindications to short-term MCS vary between devices.[4]
- **Exclusions:** None.

Medical Necessity Criteria

Indications

➔ **Percutaneous Ventricular Assist Devices** (short-term or temporary devices) are considered appropriate if **ANY** of the following is **TRUE**[3-7]:

- ◆ The patient has New York Heart Association (NYHA) Class IV heart failure and **ANY** of the following:
  - **ALL** of the following:
    - Left ventricular ejection fraction (LVEF) less than or equal to 25%; **AND**
    - Inotrope dependent;**OR**
  - Have a Cardiac Index (CI) less than 2.2 L/min/m2, while not on inotropes, and also meet **ANY** of the following:
    - Are on optimal medical management (OMM), based on current heart failure practice guidelines for at least 45 out of the last 60 days and are failing to respond; **OR**

        - Have advanced heart failure (NYHA Class IV) for at least 14 days and are dependent on an intra-aortic balloon pump or similar temporary mechanical circulatory support for at least 7 days; **OR**
    - Adjunct for high-risk percutaneous coronary interventions (severe LV dysfunction [EF less than 20% to 30%] and complex coronary artery disease involving a large territory [sole-remaining vessel, left main, or three-vessel disease])[2-3]; **OR**
    - Cardiogenic shock (LV, RV, or both); **OR**
    - Ischemic mitral regurgitation; **OR**
    - Acute reversible cardiomyopathies (myocarditis, stress cardiomyopathy, peripartum cardiomyopathy); **OR**
    - Primary cardiac transplant allograft failure due to rejection; **OR**
    - Post-transplant RV failure; **OR**
    - Patients slow to wean from cardiopulmonary bypass following heart surgery; **OR**
    - Refractory arrhythmias.

Non-Indications

➔ **Percutaneous Ventricular Assist Devices** may not be considered appropriate if **ANY** of the following is **TRUE**[1]:

- ◆ Uncontrolled sepsis; **OR**
- ◆ Bleeding diathesis; **OR**
- ◆ Severe aortic or PAD; **OR**
- ◆ The patient has an irreversible end-organ injury/multi-organ failure, including renal, hepatic, or neurological systems, and the procedure will have no benefit.

Level of Care Criteria

Inpatient

Procedure Codes (HCPCS/CPT)

HCPCS/CPT Code	Code Description
33990	Insertion of percutaneous arterial ventricular assist device by arterial access only
33991	Insertion of percutaneous arterial ventricular assist

	device by arterial and venous access, with transseptal puncture, with radiological supervision and interpretation
33995	Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; right heart, venous access only

Medical Evidence

National and Professional Organizations

Kirklin et al. (2020) published guidelines for mechanical circulatory support on behalf of the American Association for Thoracic Surgery and the International Society for Heart and Lung Transplantation. It was recommended to fully evaluate both cardiac and non-cardiac physical function and organ systems pre-operatively. Psychosocial issues should be identified and addressed. Biventricular support should be considered for patients who remain in refractory biventricular failure or who are experiencing persistent destabilizing ventricular dysrhythmias.[1]

In a 2022 clinical practice guideline on the management of heart failure for the American Heart Association and The American College of Cardiology, Heidenreich et al. make a strong recommendation for mechanical circulatory support. Select patients with heart failure with reduced ejection fraction with New York Heart Association class IV symptoms who are dependent upon continuous intravenous inotropes or temporary mechanical circulatory support may be appropriate for durable left ventricular assist device implantation.[2]

Rihal et al. (2015) developed a multi-society expert consensus document for the use of percutaneous mechanical circulatory support devices in cardiovascular care. At the time of publication, a limited number of randomized clinical trials existed. The PROTECT 2 trial was discussed, which at the time was the largest single randomized trial ever performed using percutaneous mechanical circulatory support, consisting of 452 symptomatic patients. The Impella device was studied in comparison with the intra-aortic balloon pump. Impella was found to provide superior hemodynamic support. It was noted that the most ill patients with the most significant hemodynamic compromise are not readily involved in large clinical trials.[3]

The Centers for Medicare and Medicaid Services (CMS) issued a National Coverage Determination (NCD 20.9.1) for ventricular assist devices (2020) with coverage for the following indications:

- Post cardiotomy (following open-heart surgery)
- Left ventricular assist devices (LVADs), which are approved for short-term (bridge-to-recovery or bridge-to-transplant)[6]

References

1. Kirklin J, Pagani F, Goldstein D, 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;159(3):865-896. DOI: 10.1016/j.jtcvs.2019.12.021.
2. Heidenreich P, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA guideline for the management of heart failure: a report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *J Am Coll Cardiol*. 2022;79:e263–e421.
3. Rihal C, Naidu S, Givertz M, et al. 2015 SCAI/ACC/HFSA/STS Clinical Expert Consensus Statement on the use of percutaneous mechanical circulatory support devices in cardiovascular care. *J Am Coll Cardiol*. 2015;65(19):e7-e26. doi:10.1016/j.jacc.2015.03.036.
4. Ravichandran P. Mechanical circulatory support in a nutshell. 2015. https://www.acc.org.
5. Peura J, Colvin-Adams M, Francis G, et al. Recommendations for the use of mechanical circulatory support: device strategies and patient selection: a scientific statement from the American Heart Association. *Circulation*. 2012;126(22):2648-2667. doi:10.1161/CIR.0b013e3182769a54.
6. Centers for Medicare and Medicaid Services. National Coverage Determination (NCD). Ventricular Assist Devices (20.9.1) Version 2. https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=360&ncdver=2&bc=0.
7. McDonagh T, Metra M, Adamo M, et al. 2021 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure. *Eur Heart J*. 2021;42(36):3599-3726. doi:10.1093/eurheartj/ehab368.

Clinical Guideline Revision History/Information

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Review History	