Cohere Medical Policy - Percutaneous Ventricular Assist Devices

Clinical Guidelines for Medical Necessity Review

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Guideline Information:

Specialty Area: Cardiovascular Disease
Guideline Name: Cohere Medical Policy - Percutaneous Ventricular Assist Devices

Date of last literature review: 1/22/2025
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Type: [**X**] Adult (18+ yo) | [**X**] Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Percutaneous Ventricular Assist Devices

Recommended Clinical Approach

A percutaneous ventricular assist device (pVAD) is utilized for temporary, short-term mechanical circulatory support (MCS). Use of this minimally-invasive technology may occur during a time of cardiac or cardiovascular compromise, such as during a high-risk cardiac procedure (elective use), in patients with cardiogenic shock, or in acute heart failure (emergent uses).[1-3] Current examples of FDA-approved pVADs include Impella and TandemHeart. pVADs have been frequently utilized instead of the more invasive intra-aortic balloon pumps during elective percutaneous coronary interventions.[4]

Medical Necessity Criteria

Indications

- ➔ **A percutaneous ventricular assist device (pVAD)** is considered appropriate as an adjunct for high-risk percutaneous coronary interventions if **ANY** of the following is **TRUE**[5-8]:
  - ◆ Severe left ventricular (LV) dysfunction (EF less than 20% to 30%); **OR**
  - ◆ Complex coronary artery disease (CAD) involving a large territory (sole-remaining vessel, left main, or three-vessel disease)[2,9-10]; **OR**
  - ◆ The planned percutaneous intervention is for a patient with a high risk for prolonged hypotension.[4]

Non-Indications

- ➔ **A percutaneous ventricular assist device (pVAD)** may not be considered appropriate if **ANY** of the following is **TRUE**[1,8,11-12]:
  - ◆ Bleeding diathesis; **OR**
  - ◆ Severe aortic or peripheral artery disease (PAD); **OR**
  - ◆ Mechanical aortic valve is present; **OR**
  - ◆ Aortic valve stenosis/calcification; **OR**
  - ◆ Atrial or ventricular septal defect.

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Level of Care Criteria

Outpatient

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

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Medical Evidence

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. granted a strong recommendation for mechanical circulatory support in emergent settings, such as in acute decompensated heart failure. 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]

Bjarnason and colleagues (2022) conducted a retrospective review of 79,176 Medicare patients undergoing PCI with either an intra-aortic balloon pump (IABP; 60% of study participants) or pVAD (40% of study participants) between 2013 and 2019. It was noted that the incidence of use of mechanical circulatory devices of either kind increased significantly (8514 in 2013 to 14,459 in 2019). They found a higher mean cost of hospitalization in patients with the pVAD compared to the IABP. The study outcome revealed there was not a lower mortality with pVAD, and there was a higher cost. It was also observed that the most critically ill patients were less likely to receive pVAD.[3]

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

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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.[4]

Lawton and colleagues (2022) published a clinical practice guideline related to coronary artery revascularization for the American College of Cardiology, the American Heart Association, and the Society for Cardiovascular Angiography and Interventions. Their recommendation for an appropriate hemodynamic support device for elective complex PCI to aid in preventing hemodynamic compromise during the procedure. The BCIS-1 study is cited, where there was no difference found in the primary composite outcome when hemodynamic support devices are used routinely in PCI. The study found that there were fewer major procedural complications with intra-aortic balloon counterpulsation (IABP). The PROTECT II study compared the Impella System with the IABP for high-risk PCI and concluded that Impella provided better hemodynamic support. The authors concluded that despite mixed findings in studies, hemodynamic support devices such as pVAD can be of benefit to select patients during complex PCI, including those with multivessel or left main disease.[10]

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Clinical Guideline Revision History/Information

Original Date: December 29, 2023		
Review History		

Version 2	01/23/2025	• Annual review and policy restructure
		• Recommended Clinical Approach section revised specifically for pVAD; other device descriptions removed
		• Removed all indications that are not related to prior authorization (those focusing on inpatient related or emergent conditions), including the following:
		  ○ Section regarding NYHA Class IV heart failure and related criteria for pVAD implant in those emergent situations
		  ○ Removed the listing of the following emergent indications:
		  ■ Cardiogenic shock (LV, RV, or both)
		  ■ Ischemic mitral regurgitation
		  ■ Acute reversible cardiomyopathies (myocarditis, stress cardiomyopathy, peripartum cardiomyopathy)
		  ■ Primary cardiac transplant allograft failure due to rejection
		  ■ Post-transplant RV failure
		  ■ Patients slow to wean from cardiopulmonary bypass following heart surgery
		  ■ Refractory arrhythmias.

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		• Removed all Non-Indications that are not related to prior authorization (those focusing on inpatient related or emergent conditions), including the following:
		  ○ Uncontrolled sepsis
		  ○ Irreversible end-organ injury/multi-organ failure, including renal, hepatic, or neurological systems, and the procedure will have no benefit.
		• No changes to procedure codes.
		• Literature review - Medical Evidence section updated to include a summary of reference number 10.
		• New/updated references added

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