

2025 Percutaneous Ventricular Assistive Device (pVAD)

Cardiology

CARD-CVAD-HH

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Cardiac Percutaneous Ventricular Assist Device (pVAD)

**NCD 20.9.1**

See also, **NCD 20.9.1**: Ventricular Assist Devices at <https://www.cms.gov/medicare-coverage-database/search.aspx> if applicable to individual's healthplan membership.

Preamble: Pediatric Cardiology Preamble

HealthHelp's clinical guidelines for the Cardiology program, are intended to apply to both adults and pediatrics (21 years of age or younger), unless otherwise specified within the criteria.

pVAD Contraindications

A percutaneous ventricular assist device (pVAD) is contraindicated for **ANY** of the following:

1. Anatomy is prohibitive.
Reference: [5]
2. Contraindication to long-term oral anticoagulation exists.
Reference: [5]
3. End-stage non-cardiac disease (eg, liver, lung, neurological, renal) is irreversible.
References: [5] [2]
4. Psychosocial limitations are severe (eg, active substance abuse, impaired cognitive function, inability to adhere to plan of care, lack of social support, unmanaged psychiatric disorder).
References: [5] [2]
5. Right ventricular failure and **NOT** responsive to optimal medical therapy.
Reference: [5]
6. Ventricular arrhythmia is uncontrolled.
Reference: [5]
7. Weight is less than 3 gm in a pediatric individual.
References: [5] [3]

pVAD Relative Contraindications

Relative contraindications for percutaneous ventricular assist device include **ANY** of the following:

1. Age is more than 80 years (for destination therapy).

Reference: [2]

2. Infection is active.

Reference: [2]

3. Intubation is prolonged.

Reference: [2]

4. Obesity or malnutrition

Reference: [2]

5. Malignancy is untreated.

Reference: [2]

6. Peripheral vascular disease (PVD) is present and severe.

Reference: [2]

7. Psychosocial limitations (eg, active substance abuse, impaired cognitive function, lack of social support, unmanaged psychiatric disorder)

Reference: [2]

8. Rehabilitation is impaired by musculoskeletal disease.

Reference: [2]

pVAD Guideline

A percutaneous ventricular assist device (pVAD) is considered medically appropriate when the documentation demonstrates **ANY** of the following:

1. Cardiogenic shock is refractory to medical management and **ANY** of the following:
 - a. Fulminant myocarditis
 - b. Heart failure (HF) is advanced (New York Heart Association [NYHA] Stage IIIb to IV or ACC/AHA Stage D), in an adult or pediatric individual, and **ANY** of the following:
 - i. Bridge to decision (BTD)
 - ii. Bridge to transplant (BTT)
 - iii. Destination therapy (DT)
 - c. Myocardial infarction (post-acute)

References: [8] [6] [1] [7] [4] [3] [5]

2. High-risk coronary artery interventions (eg, percutaneous coronary intervention [PCI])¹

Reference: [8]

¹High-risk candidates for percutaneous coronary intervention (PCI) may include individuals with severe multi-vessel coronary artery disease, left main coronary artery stenosis without collateral circulation or stenting, or members with a

pVAD Procedure Codes

Table 1. Percutaneous Ventricular Assistive Device (pVAD) Associated Procedure Codes

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 transeptal 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

pVAD Summary of Changes

Cardiac Percutaneous Ventricular Assistive Device (pVAD) clinical guidelines from 2024 to 2025 had the following version changes:

- Added the following to keep in line with current evidence:
 - "Infection is active" under Relative Contraindications
 - "Obesity or malnutrition" under Relative Contraindications
 - Pediatric preamble
 - "Psychosocial limitations" under Relative Contraindications
 - "Rehabilitation is impaired by musculoskeletal disease" under Relative Contraindications
- Removed the following as current evidence no longer supports the indication:
 - "Mural thrombus is present" from under Contraindications
 - "Tricuspid regurgitation is severe" from under Contraindications

pVAD Definitions

American College of Cardiology (ACC)/American Heart Association (AHA) Stages of Heart Failure

left ventricular (LV) ejection fraction of $\leq 35\%$. Ventricular support devices may be indicated for use during high-risk PCI performed in elective or urgent, hemodynamically stable members with severe CAD when a heart team, including a cardiac surgeon, has determined high-risk PCI is the appropriate option.

- **Stage A:** At-risk for heart failure (HF) but without symptoms, structural heart disease or cardiac biomarkers of stretch or injury (eg, hypertension, atherosclerotic cardiovascular disease (CVD), diabetes, metabolic syndrome and obesity, exposure to cardiotoxic agents, genetic variant for cardiomyopathy or family history of cardiomyopathy).
- **Stage B:** Pre-heart failure, without current or previous symptoms or signs of HF but evidence of one of the following: structural heart disease, evidence of increasing filling pressures, risk factors and increased natriuretic peptide levels or persistently elevated cardiac troponin in the absence of competing diagnoses.
- **Stage C:** Symptomatic heart failure is structural heart disease with current or previous symptoms of HF.
- **Stage D:** Advanced heart failure has marked HF symptoms that interfere with daily life and with recurrent hospitalization despite attempts to optimize guideline-directed medical therapy (GDMT).

Anticoagulation is a substance that is used to prevent and treat blood clots in blood vessels and the heart.

Bridge to candidacy is the use of a long term device (eg, mechanical circulatory support, ventricular assist device, total artificial heart) in an individual who is not yet on the heart transplantation list and their eligibility for transplant has yet to be determined.

Bridge to decision is the use of a short term device (eg, mechanical circulatory support, ventricular assist device) in a member who requires support while awaiting further treatment decision(s).

Bridge to transplantation is the use of a long term device (eg, mechanical circulatory support, ventricular assist device, total artificial heart) to preserve an individual's health until they are able to have organ transplantation.

Cardiogenic shock (CS) is a serious and life-threatening condition that occurs when the heart is unable to pump enough blood to the body's vital organs and is commonly triggered by heart attack or heart failure.

Coronary artery disease (CAD) is caused by plaque buildup in the walls of the arteries that supply blood to the heart (called coronary arteries) and other parts of the body.

Destination therapy is the use of a long term device (eg, mechanical circulatory support, total artificial heart, ventricular assist device) in an individual who will not require or does not qualify for any additional treatment.

Fulminant is a description for any process that occurs suddenly and escalates quickly, intense, and severe to the point of being lethal.

Heart failure (HF) (also known as **congestive heart failure [CHF]**) is a condition that develops when the heart is unable to pump enough blood for the body's needs. HF occurs when the heart cannot fill with enough blood or is too weak to pump properly. Decompensated heart

failure is sudden worsening (exacerbation) of heart failure symptoms (eg, difficulty breathing, lower extremity edema, fatigue) to where the heart can no longer continue to compensate for its full function.

Impaired cognitive function, also known as cognitive impairment, is a medical term for problems with thinking, learning, and memory. It can affect a person's ability to understand, reason, and make decisions.

Left ventricular ejection fraction (LVEF), also known as ejection fraction (EF), measures the amount of blood the left ventricle of the heart pumps out to the body with each heartbeat.

Malignant is the presence of cancerous cells that have the ability to spread to other sites in the body (metastasize) or to invade nearby (locally) and destroy tissues. Malignant cells tend to have fast, uncontrolled growth and do not die normally due to changes in their genetic makeup.

Musculoskeletal disease is a medical term for conditions that affect the muscles, bones, joints, and connective tissues. These conditions can range from minor injuries to long-term conditions.

Myocardial infarction (MI), also called a heart attack, occurs when the blood flow that brings oxygen to the heart muscle is severely reduced or cut off completely. The coronary arteries that supply the heart muscle with blood flow can become narrowed from a buildup of fat, cholesterol and other substances that together are called plaque. This process is known as atherosclerosis. When plaque within a coronary artery breaks, a blood clot forms around the plaque and can block the flow of blood through the artery to the heart muscle. Ischemia results when there is an inadequate blood supply to the heart muscle causing damage or death of part of the heart muscle, resulting in an MI.

Myocarditis is inflammation of the muscle tissue of the heart (myocardium) that causes tissue death. Myocarditis may be caused by many disorders, including infection, toxins and drugs that affect the heart, and systemic disorders such as sarcoidosis, but often the cause is unknown. ²

Table 1. New York Heart Association (NYHA) Functional Classification for Heart Failure

CLASS	SYMPTOMS EXPERIENCED
Class I (Mild)	Cardiac disease, but no symptoms and no limitation in ordinary physical activity (eg, shortness of breath when walking, climbing stairs).
Class II (Mild)	Mild symptoms (eg, mild shortness of breath and/or angina) and slight limitation during ordinary activity.
Class III (Moderate)	Marked limitation in activity due to symptoms, even during less-than-ordinary activity, (eg, walking short distances [20–100 m]). Comfortable only at rest. Class IIIa: no dyspnea at rest. Class IIIb: recent dyspnea at rest.
Class IV (Severe)	Severe limitations. Experience symptoms while at rest. Unable to carry on any physical activity without discomfort.

Percutaneous describes something that is occurring within or performed through the skin.

²Merck & Co, Inc., "Myocarditis". [Online]. Available: www.merckmanuals.com

Percutaneous coronary intervention (PCI) is a non-surgical procedure that uses a catheter (a thin flexible tube) to place a small structure called a stent to open up blood vessels in the heart that have been narrowed by plaque buildup, a condition known as atherosclerosis.

Percutaneous ventricular assist device (PVAD) is a small mechanical pump that provides temporary support for a weakened heart. It's inserted into a blood vessel through a catheter and worn outside the body.

Peripheral vascular disease is a blood circulation disorder that causes the blood vessels outside of the heart and brain to narrow, block or spasm.

Post- acute is a range of medical care services that support the individual's continued recovery from illness or management of a chronic illness or disability.

Prohibitive anatomy is a complication in the structural makeup of the body or body parts that hinders the ability to access or alter it.

Refractory is resistance to treatment or cure.

Right ventricular dysfunction is condition in which the muscle of the right ventricle is not pumping as efficiently as it should be. This can be caused by a number of conditions, including left sided heart failure, high blood pressure in the lungs and heart valve disease.

Ventricular arrhythmia is an abnormal heart rhythm that makes the lower chambers of the heart twitch instead of pump, which can limit or stop your heart from supplying blood to your body.

Ventricular assist device (VAD) is a type of implantable mechanical circulatory support device designed to help pump blood from the heart to the rest of the body. A VAD is used in people who have weakened hearts or heart failure. Percutaneous VADs are inserted with a catheter through a blood vessel and do not require open heart surgery.

pVAD References

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Disclaimer section

Purpose

The purpose of the HealthHelp's clinical guidelines is to assist healthcare professionals in selecting the medical service that may be appropriate and supported by evidence to safely improve outcomes. Medical information is constantly evolving, and HealthHelp reserves the right to review and update these clinical guidelines periodically. HealthHelp reserves the right to include in these guidelines the clinical indications as appropriate for the organization's program objectives. Therefore the guidelines are not a list of all the clinical indications for a stated procedure, and associated Procedure Code Tables may not represent all codes available for that state procedure or that are managed by a specific client-organization.

Clinician Review

These clinical guidelines neither preempt clinical judgment of trained professionals nor advise anyone on how to practice medicine. Healthcare professionals using these clinical guidelines are responsible for all clinical decisions based on their assessment. All Clinical Reviewers are instructed to apply clinical indications based on individual patient assessment and documentation, within the scope of their clinical license.

Payment

The use of these clinical guidelines does not provide authorization, certification, explanation of benefits, or guarantee of payment; nor do the guidelines substitute for, or constitute, medical

advice. Federal and State law, as well as member benefit contract language (including definitions and specific contract provisions/exclusions) take precedence over clinical guidelines and must be considered first when determining eligibility for coverage. All final determinations on coverage and payment are the responsibility of the health plan. Nothing contained within this document can be interpreted to mean otherwise.

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National and Local Coverage Determination (NCD and LCD)



NOTICE

To ensure appropriate review occurs to the most current NCD and/or LCD, always defer to <https://www.cms.gov/medicare-coverage-database/search.aspx>.

Background

National Coverage Determinations (NCD) and Local Coverage Determinations (LCD) are payment policy documents outlined by the Centers for Medicare and Medicaid Services (CMS) and the government's delegated Medicare Audit Contractors (MACs) that operate regionally in jurisdictions.

CMS introduced variation between different jurisdictions/Medicare Audit Contractors (MACs) and their associated covered code lists with the transition to ICD 10. The variation resulted in jurisdictions independently defining how codes are applied for exclusions, limitations, groupings, ranges, etc. for the medical necessity indications outlined in the NCD and LCD. Due to this variation, there is an inconsistent use/application of codes and coverage determinations across the United States between the different MACs.

In addition, **WITHOUT** notice, CMS can change the codes that indicate medical necessity and the format of the coverage determinations/associated documents (eg, Articles). This is an additional challenge for organizations to keep up with ongoing, unplanned changes in covered codes and medical necessity indications.



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Medical Necessity Codes

Due to the variation in code application between jurisdictions/MACs and that updates can happen without notification, HealthHelp is not able to guarantee full accuracy of the codes listed for any Coverage Determination, and advises that prior to use, the associated Coverage Determination Articles are reviewed to ensure applicability to HealthHelp's programs and any associated NCDs and LCDs.

For Internal Use Only:

11248 11249 11253 11282 11325 11328 11333 11349 11350 11351 11352 11354 11355 11356
11358 11359 11360 11361 11362 11365 11366 11367 11368 11369 11370 11374 11375 11394
11395 11396 11565