Medical Policy Reference Manual
Medical Policy

7.03.011 Ventricular Assist Devices and Associated Services

Original MPC Approval: 04/01/1998
Last Review: 08/01/2023
Last Revision: 02/01/2024

Description

A ventricular assist device (VAD), also called ventricular assist system (VAS) or left ventricular assist device (LVAD), is a mechanical pump that helps a weakened heart pump blood throughout the body. The LVAD does not replace the heart. It assists the patient's own heart to pump blood, decreasing the work of the left ventricle. The LVAD is attached to the apex of the left ventricle and to the aorta. When the left ventricle contracts, blood flows into the LVAD pump. When the heart relaxes, the left ventricle fills with blood, and the blood in the device is pumped into the aorta.

Ventricular assist devices (VADs) represent a method of providing temporary mechanical circulatory support (MCS) for those patients not expected to survive until a heart becomes available for their transplant. The scarcity of donor organs has led to the development of interim interventions (mechanical assist devices). VADs may also be used as interim circulatory therapy for cardiac trauma/injury while the heart heals or to support cardiac function in appropriate patients who are not eligible for transplant (destination therapy) Heidenreich, P. A., et al (2022).

A variety of devices have received approval for marketing from the U.S. Food and Drug Administration (FDA), encompassing both biventricular and left ventricular devices, as well as devices that are intended to be used in the hospital setting alone and those that can be used as an outpatient.

NOTE: This policy does not address the percutaneous left ventricular assist devices. See Medical Policy 7.01.122 Percutaneous Left Ventricular Assist Device (pLVAD).

Policy

Unless contraindicated, ventricular assistance is considered **medically necessary**, using an FDA approved device, for the following indications:

- when used as a bridge to decision for heart transplant;
- when used as a bridge to recovery for patients who are unable to be weaned from cardiopulmonary bypass and are likely to recover cardiac function after the myocardium is permitted to rest;
- as destination therapy in patients with treatment resistant end-stage heart failure (New York Heart Association (NYHA) class IIIB or IV) with an ejection fraction of <25%.

The use of ventricular assist devices for other indications is considered **not medically necessary.**

Policy Guidelines

Contraindications to VAD destination therapy include:

- irreversible and severe impairment of cognitive function
- inability to maintain treatment adherence
- any medical condition except for heart failure where life expectancy is less than 1 year.
- presence of systemic infection/sepsis
- moderate to severe aortic insufficiency that remains uncorrected
- severe right ventricular failure that is not secondary to left ventricular disease
- inability to tolerate anticoagulation after repeated attempts and/or irreversible coagulopathy
- patient not appropriate for long-term anticoagulation

- heart failure that will improve without MCS

Rationale:
The VAD is used for those patients whose medical therapy has failed and are hospitalized with end-stage systolic heart failure. Published studies continue to report that the use of a VAD does not compromise the success of a subsequent heart transplant and, in fact, may improve post-transplant survival, thus improving the utilization of donor hearts.

Update 2023: A search of the peer-reviewed literature was performed from the period of November 2019 through February 2023. Findings in the recent literature support the medically necessary indications for ventricular assist devices listed in the Policy section of this document. For all other indications ventricular assist devices are considered not medically necessary. On June 3, 2021, after an alert from the FDA, Medtronic ceased production and sale of its HeartWare® Ventricular Assist Device (HVAD system). On August 6, 2021, the FDA officially issued a Class I recall of the Medtronic HeartWare® device related to an elevated risk of neurological adverse events and mortality associated with the internal pump as well as the potential for the internal pump to stop where the pump has delayed start or failure to restart which may cause death or severe harm (FDA, 2021).

Update 2019: A search of the peer-reviewed literature was performed from the period of November 2017 through November 2019. Findings show, on May 2, 2018, the FDA issued a recall on Medtronic HeartWare® Ventricular Assist Device (HVAD system) due to interference to the electrical connection. Interruption to the connection could potentially stop resulting in mild to serious events such as exacerbation of heart failure symptoms, mild weakness, dizziness, anxiety, nausea, loss of consciousness, or death. The devices affected were manufactured and distributed from March 2006 to May 2018. FDA product codes are 204 and 017. In addition, a recall was issued on April 5, 2018, for Abbott HeartMate 3™ (LVAD) due to twisting of the outflow graft resulting in a persistent low flow alarm.

Update 2017: A search of the peer-reviewed literature was performed for the period of November 2015 through October 2017. Findings in the recent literature do not change the conclusions on the use of ventricular assist devices for conditions other than those medically necessary indications listed in the Policy section of this document. Therefore, the policy statements are unchanged.

Update 2015: A search of the peer-reviewed literature was performed for the period of October 2013 through October 2015. Findings in the recent literature do not change the conclusions on the use of ventricular assist devices for conditions other than those medically necessary indications listed in the Policy section of this document. Therefore, the policy statements are unchanged.

Update 2013: A search of the peer-reviewed literature was performed for the period of May 2011 through September 2013. Findings in the recent literature do not change the conclusions on the use of ventricular assist devices for conditions other than those medically necessary indications listed in the Policy section of this document. Therefore, the policy statements are unchanged.

Update 2011: A search of the peer-reviewed literature was performed for the period of April 2009 through April 2011. Findings in the recent literature do not change the conclusions on the use of ventricular assist devices for conditions other than those medically necessary indications listed in the Policy section of this document. Therefore, the policy statements are unchanged.

Update 2009: A search of the peer-reviewed literature was performed for the period of January 2007 through March 2009. Findings in the recent literature do not change the conclusions on the use of ventricular assist devices for conditions other than those medically necessary indications listed in the Policy section of this document. Therefore, the policy statements are unchanged.

Update 2007: A search of the peer-reviewed literature was performed for the period of January 2005 through January 2007. Findings in the recent literature do not change the conclusions on the use of VAD for conditions other than those medically necessary indications listed in the Policy section of this document. Therefore, the policy statements are unchanged.

Benefit Applications

The purpose of this Medical Policy Reference Manual is to provide clinical criteria and/or local, state, or federal coverage requirements for applicable services, devices, and drugs. Specific contract provisions, restrictions, and exclusions will take precedence over the clinical criteria, as the member contract supersedes clinical criteria adopted by CareFirst. Some services, devices, drugs, and places of service require prior authorization. Always check the member's contract for benefits.

Provider Guidelines

There are no Provider Guidelines for this Medical Policy.

Cross References to Related Policies and Procedures

7.01.122 Percutaneous Left Ventricular Assist Device (pLVAD), Policy

References

The following were among the resources reviewed and considered in developing this policy. By reviewing and considering the resources, CareFirst does not in any way endorse the contents thereof nor assume any liability or responsibility in connection therewith. The opinions and conclusions of the authors of these resources are their own and may or may not be in agreement with those of CareFirst.

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