National Coverage Determination (NCD) 20.9.1
Ventricular Assist Devices (VADs)

MLN Matters Number: MM12290
Related Change Request (CR) Number: 12290
Related CR Release Date: June 11, 2021
Effective Date: December 1, 2020
Related CR Transmittal Number: R10837CP
Implementation Date: July 27, 2021
and R10837NCD

Provider Types Affected

This MLN Matters Article is for physicians and providers billing MACs for VAD services they provide to Medicare beneficiaries.

Provider Action Needed

This Article tells you that, effective December 1, 2020, CMS covers VADs under certain criteria. CR 12290 revises the relevant sections of:

- Chapter 1, Part 1, Section 20.9 of the Medicare NCD Manual
- Chapter 32, Section 320 of the Medicare Claims Processing Manual

The CR transmittals contain the revised chapters as attachments. Be sure your billing staffs are aware of these changes.

Background

In 1993, CMS first issued an NCD providing limited coverage of VADs and we have expanded the policy over the years. We last reconsidered this NCD in 2013.

VADs or left ventricular assist devices (LVADs) are mechanical blood pumps that are surgically attached to 1 or both intact ventricles of a damaged or weakened native heart to assist in pumping blood.

Medicare covers LVADs if the FDA approves them for short-term (for example, bridge-to-recovery and bridge-to-transplant) or long-term (for example, destination therapy) mechanical circulatory support for heart failure patients meeting the following criteria:

- Have New York Heart Association (NYHA) Class IV heart failure; and
- Have a left ventricular ejection fraction (LVEF) ≤ 25%; and
• Are inotrope dependent
  OR
  have a Cardiac Index (CI) < 2.2 L/min/m2 while not on inotropes and meet 1 of the following:
  o 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
  o Have advanced heart failure for at least 14 days and are dependent on an intra-aortic balloon pump (IABP) or similar temporary mechanical circulatory support for at least 7 days

An explicitly identified, cohesive, multidisciplinary team of medical professionals with appropriate qualifications, training, and experience must manage patients receiving a VAD. The team must make sure that patients and caregivers have the knowledge and support necessary to participate in informed decision making. The team members must be based at the facility and must include individuals with experience working with patients before and after placement of a VAD.

The team must include, at a minimum:

• At least 1 physician with cardiothoracic surgery privileges and individual experience implanting at least 10 durable, intracorporeal, LVADs over the course of the previous 36 months with activity in the last year
• At least 1 cardiologist trained in advanced heart failure with clinical competence in medical-based and device-based management, including VADs, and clinical competence in the management of patients before and after placement of a VAD
• A VAD program coordinator
• A social worker
• A palliative care specialist

To learn how organizations apply for CMS approval to be designated as a credentialing organization for VAD facilities, visit the CMS VAD Therapy Facilities page. This page also includes:

• A list of approved credentialing organizations
• Approved standard versions
• Credentialed facilities

**More Information**

We issued CR 12290 to your MAC as the official instruction for this change. The CR consists of 2 transmittals. The first transmittal updates the NCD Manual. The second transmittal updates the Medicare Claims Processing Manual. Both manual updates include a list of HCPCS codes related to the VADs.

For more information, contact your MAC.
Document History

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<tr>
<th>Date of Change</th>
<th>Description</th>
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<tr>
<td>June 14, 2021</td>
<td>Initial article released.</td>
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