



The Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program is scheduled to begin in nine competitive bidding areas (CBAs) on January 1, 2011. Referral agents located in CBAs who prescribe DMEPOS for beneficiaries or refer beneficiaries to specific suppliers will need to be aware of which suppliers in the area are contract suppliers as well as other important referring information. Referral agents include such entities as Medicare enrolled providers, physicians, treating practitioners, discharge planners, social workers, and pharmacists who refer beneficiaries for services in a CBA. More information for referral agents can be found in the new Medicare Learning Network® (MLN) fact sheet “The DMEPOS Competitive Bidding Program: Fact Sheet for Referral Agents” located at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/index.html> on the CMS website. This fact sheet is also available to order in hardcopy, free of charge. To order your copy, please visit the MLN homepage at <http://www.cms.gov/mlngeninfo> on the CMS website.

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Related Change Request (CR) #: 7220

Related CR Release Date: December 8, 2010

Effective Date: November 9, 2010

Related CR Transmittal #: R129NCD

Implementation Date: January 11, 2011

Ventricular Assist Devices (VADs) as Destination Therapy

Note: This article was updated on September 18, 2014, to add a link to MLN Matters® article MM8803 available at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM8803.pdf> on the CMS website. This article alerts providers that CMS is modifying the criteria for coverage of ventricular assist devices (VADs) as Bridge-to-Transplant (BTT) and is modifying the facility criteria for coverage as destination Therapy (DT).. All other information is the same..

Provider Types Affected

This article is for physicians, providers, and suppliers submitting claims to Medicare contractors (carriers, Fiscal Intermediaries (FIs), and/or A/B Medicare Administrative Contractors (A/B MACs)) for Ventricular Assist Device (VAD) implantation services provided to Medicare beneficiaries.

Disclaimer

This article was prepared as a service to the public and is not intended to grant rights or impose obligations. This article may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either the written law or regulations. We encourage readers to review the specific statutes, regulations and other interpretive materials for a full and accurate statement of their contents.

What You Need to Know

Effective for claims with dates of service on or after November 9, 2010, The Centers for Medicare & Medicaid Services (CMS) has expanded coverage for VAD implantation as destination therapy as reasonable and necessary when the device has received Food and Drug Administration (FDA) approval for a destination therapy indication and only for patients with New York Heart Association (NYHA) Class IV end-stage ventricular heart failure who are not candidates for a heart transplant and who meet all specific conditions as outlined in the revised **Medicare National Coverage Determinations (NCD) Manual** (Chapter 1, Section 20.9).

Background

A Ventricular Assist Device (VAD) or Left Ventricular Assist Device (LVAD) is surgically attached to one or both intact ventricles and is used to assist a damaged or weakened native heart in pumping blood. Medicare currently covers these devices for three general indications:

1. Postcardiotomy,
2. Bridge to transplantation, and
3. Destination therapy.

Destination therapy is for patients who are not candidates for heart transplantation and require permanent mechanical cardiac support. Coverage for destination therapy is currently restricted based on patient selection criteria including:

- New York Heart Association (NYHA) class,
- Time on optimal medical management,
- Left ventricular ejection fraction, and
- Peak oxygen consumption.

NOTE: VADs implanted for destination therapy are only covered when performed in a hospital that is Medicare approved to provide this procedure.

CR 7220 instructs that, effective for claims with dates of service on and after November 9, 2010, CMS has determined that the evidence is adequate to conclude that VAD implantation as destination therapy improves health outcomes and is reasonable and necessary when:

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- The device has received FDA approval for a destination therapy indication, and only for patients with New York Heart Association (NYHA) Class IV end-stage ventricular heart failure who are not candidates for heart transplant, and
- Who meet all of the following conditions:
 - Have failed to respond to optimal medical management (including beta-blockers, and Antiotensin-Converting Enzyme (ACE) inhibitors if tolerated) for at least 45 of the last 60 days, or have been balloon pump-dependent for 7 days, or IV inotrope-dependent for 14 days;
 - Have a Left Ventricular Ejection Fraction (LVEF) < 25%; and,
 - Have demonstrated functional limitation with a peak oxygen consumption of ≤14 ml/kg/min unless balloon pump or inotrope dependent or physically unable to perform the test.

Note: There are no changes to existing claims processing requirements/editing for VADs as destination therapy.

Additional Information

The official instruction, CR 7220, issued to your carriers, FIs, and A/B MACs regarding this change may be viewed at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R129NCD.pdf> on the CMS website.

If you have any questions, please contact your carriers, FIs, or A/B MACs at their toll-free number, which may be found at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/provider-compliance-interactive-map/index.html> on the CMS website.

News Flash - Each Office Visit is an Opportunity. Medicare patients give many reasons for not getting their annual flu vaccination, but the fact is that there are 36,000 flu-related deaths in the United States each year, on average. More than 90% of these deaths occur in people 65 years of age and older. Please talk with your Medicare patients about the importance of getting their annual flu vaccination. This Medicare-covered preventive service will protect them for the entire flu season. And remember, vaccination is important for health care workers too, who may spread the flu to high risk patients. **Don't forget to immunize yourself and your staff. Protect your patients. Protect your family. Protect yourself. Get Your Flu Vaccine - Not the Flu.** Remember – Influenza vaccine plus its administration are covered Part B benefits. Note that influenza vaccine is NOT a Part D covered drug. For information about Medicare's coverage of the influenza vaccine and its administration, as well as related educational resources for health care professionals and their staff, please visit http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/Flu_Products.pdf and <http://www.cms.gov/Medicare/Prevention/Immunizations/index.html> on the CMS website.

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