



If you treat a Medicare Advantage enrolled beneficiary and you have questions about their Medicare Advantage Plan, you may wish to contact that plan. A plan directory and MA claims processing contact directory are available at <http://www.cms.hhs.gov/MCRAdvPartDEnrolData/> on the CMS website. CMS updates this site on a monthly basis.

MLN Matters Number: MM5516

Related Change Request (CR) #: 5516

Related CR Release Date: April 13, 2007

Effective Date: March 27, 2007

Related CR Transmittal #: R68NCD

Implementation Date: May 14, 2007

## Ventricular Assist Devices (VADs)

### Provider Types Affected

Physicians and providers submitting claims to Medicare contractors (carriers, Fiscal Intermediaries (FIs), Part A/B Medicare Administrative Contractors (A/B MACs)) for services provided to Medicare beneficiaries.

### Provider Action Needed



#### STOP – Impact to You

This article is based on Change Request (CR) 5516 which announces that, effective March 27, 2007, new facility criteria are established and hospitals must receive certification from the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) under their Disease Specific Certification Program for Ventricular Assist Devices (VADs). The new criteria apply to hospitals that implant VADs for the destination therapy indication.



#### CAUTION – What You Need to Know

Currently approved hospitals will have until March 27, 2009, to become certified by the JCAHO or they will be removed from the approved list.



#### GO – What You Need to Do

See the Background and Additional Information Sections of this article for further details regarding these changes.

#### 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.

## Background

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A VAD is an implantable device used to assist a damaged or weakened heart in pumping blood. These devices are used for support of blood circulation 1) post-cardiotomy, 2) as a bridge to a heart transplant, or 3) as destination therapy. Destination therapy is defined as use of a device as the end result of treatment (i.e., permanent transplantation), instead of a “bridge” to transplantation. Destination therapy is an indication for patients that are not heart transplant eligible, and therefore, they expect to require use of the VAD through the end of life.

Through a National Coverage Determination (NCD) Manual (Publication 100-03), Section 20.9, “Artificial Hearts and Related Devices”) issued on October 14, 2003 (CR 2958, Transmittal 2;

<http://www.cms.hhs.gov/Transmittals/Downloads/R2NCD.pdf>), Medicare began coverage of the destination therapy indication. The 2003 decision established hospital criteria and an application process through which hospitals were required to submit information to the Centers for Medicare & Medicaid Services (CMS). If approved, the hospital(s) were listed as an approved VAD destination therapy hospital on the CMS website (<http://www.cms.hhs.gov/MedicareApprovedFacilitie/VAD/list.asp#TopOfPage>). At that time, Medicare contractors were instructed to use this VAD Destination Therapy Facilities website to determine which hospitals in their area were Medicare approved for VADs as destination therapy.

CR 5516 announces that, effective March 27, 2007, new facility criteria are established. Included in the facility criteria are requirements that:

- Facilities must have at least one member of the VAD team with experience implanting at least 10 VADs (as bridge to transplant or destination therapy) or artificial hearts over the course of the previous 36 months;
- Facilities must be a member of the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS); and
- By March 27, 2009, all facilities must meet the updated CMS facility criteria and be credentialed by the JCAHO under their Disease Specific Certification Program for VADs (standards dated February 2007).

The VAD Destination Therapy Facilities website will be continuously updated by CMS to maintain a current list of approved facilities. Medicare contractors will continue to use this website to determine which hospitals are covered by Medicare when VADs are implanted as destination therapy.

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## Additional Information

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The official instruction, CR5516, issued to your carrier, intermediary, or A/B MAC regarding this change may be viewed at <http://www.cms.hhs.gov/Transmittals/downloads/R68NCD.pdf> on the CMS website.

If you have any questions, please contact your Medicare carrier, intermediary, or A/B MAC at their toll-free number, which may be found on the CMS website at <http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip>.

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