

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Centers for Medicare & Medicaid Services



REVISED product from the Medicare Learning Network® (MLN)

- [“Screening, Brief Intervention, and Referral to Treatment \(SBIRT\) Services”](#) Fact Sheet, ICN 904084, Downloadable only.

MLN Matters® Number: MM8803

Related Change Request (CR) #: CR 8803

Related CR Release Date: August 29, 2014

Effective Date: October 30, 2013

Related CR Transmittal #:R172NCD and R3054CP

Implementation Date: September 30, 2014

## Ventricular Assist Devices for Bridge-to-Transplant and Destination Therapy

### Provider Types Affected

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This MLN Matters® Article is intended for physicians, other providers, and suppliers who submit claims to Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

### Provider Action Needed

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This article is based on Change Request (CR) 8803 which instructs that, effective for claims with dates of service on and after October 30, 2013, the Centers for Medicare & Medicaid Services (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). Make sure your billing staffs are aware of these changes.

### Background

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CR 8803 states that Medicare covers VADs for the following three general indications:

#### Disclaimer

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1. Postcardiotomy - Postcardiotomy refers to the placement of VADs following open-heart surgery.
2. Bridge-to-transplantation (BTT) - Coverage for BTT is restricted to patients listed for heart transplantation; and,
3. Destination therapy (DT) - Coverage for DT is restricted to patients who are not candidates for heart transplantation, require mechanical cardiac support, and who meet specific clinical criteria.

Note: VADs implanted as DT are only covered when implanted in a facility that is approved by CMS to provide this procedure.

Effective for claims with dates of service on and after October 30, 2013, CMS has determined that the evidence is adequate to conclude that VAD implantation is reasonable and necessary with the following modifications to current CMS policy at 20.9.1:

- **VADs for BTT:** CMS clearly identifies that the patient must be active on the wait list maintained by the Organ Procurement and Transplantation Network and removes the general time requirement that patients receive a transplant as soon as medically reasonable.
- **VADs for DT:** CMS expands the credentialing requirement to allow credentialing by other organizations approved by Medicare and include requirements for a multidisciplinary team. CMS removes mandatory participation in the INTERMACS registry, but encourages facilities to track patient outcomes.

Note that coverage for items and services under the Social Security Act (the Act) (section 1862(a)(1)(A); see [http://www.ssa.gov/OP\\_Home/ssact/title18/1862.htm](http://www.ssa.gov/OP_Home/ssact/title18/1862.htm)) in these situations will be made by your MAC within its jurisdiction.

CR 8803 revises the "Medicare National Coverage Determinations (NCD) Manual" (Chapter 1) by revising section 20.9 (Artificial Hearts and Related Devices) and adding a new sub-section (20.9.1) titled 'Ventricular Assist Devices.'

CR 8803 also revises the "Medicare Claims Processing Manual" (Chapter 32, Section 320 (Artificial Hearts and Related Devices). ICD-10 codes related to these services are included in this manual update. The revised portions of these two manuals are available as attachments to CR 8803.

All other indications for the use of VADs not otherwise listed remain non-covered, except in the context of Category B investigational device exemption clinical trials (42 CFR 405) or as a routine cost in clinical trials defined under section 310.1 of the NCD Manual.

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This policy does not address coverage of VADs for right ventricular support, biventricular support, use in beneficiaries under the age of 18, use in beneficiaries with complex congenital heart disease, or use in beneficiaries with acute heart failure without a history of chronic heart failure. Coverage under section 1862(a)(1)(A) of the Act for VADs in these situations will be made by your MAC.

## Additional Information

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The official instruction, CR 8803, consists of two transmittals issued to your MAC. The first transmittal updates the NCD Manual and it is available at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R172NCD.pdf> on the CMS website. The second transmittal updates the “Medicare Claims Processing Manual” and is available at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3054CP.pdf> on that site.

If you have any questions, please contact your MAC at their toll-free number. That number is available at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Net-work-MLN/MLNMattersArticles/index.html> under - How Does It Work.

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