

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-03 Medicare National Coverage Determinations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 68	Date: APRIL 13, 2007
	Change Request 5516

SUBJECT: Ventricular Assist Devices (VADs)

I. SUMMARY OF CHANGES: Effective March 27, 2007, new facility criteria is established and hospitals must now receive certification from the Joint Commission on Accreditation of Healthcare Organizations under their Disease Specific Certification Program for VADs. Currently approved hospitals will have until March 27, 2009, to become certified by the Joint Commission or they will be removed from the approved list.

This revision is a national coverage determination (NCD). NCDs are binding on all carriers, fiscal intermediaries, quality improvement organizations, qualified independent contractors, the Medicare Appeals Council, and administrative law judges (ALJs) (see 42 CFR section 405.1060(a)(4) (2005)). An NCD that expands coverage is also binding on a Medicare advantage organization. In addition, an ALJ may not review an NCD. (See section 1869(f)(1)(A)(i) of the Social Security Act.)

NEW / REVISED MATERIAL

EFFECTIVE DATE: March 27, 2007

IMPLEMENTATION DATE: May 14, 2007

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	1/Table of Contents
R	1/20.9/Artificial Hearts and Related Devices (Effective March 27, 2007)

III. FUNDING:

No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2007 operating budgets.

IV. ATTACHMENTS:

**Business Requirements
Manual Instruction**

**Unless otherwise specified, the effective date is the date of service.*

Attachment - Business Requirements

Pub. 100-03 | Transmittal: 68 | Date: April 13, 2007 | Change Request: 5516

SUBJECT: Ventricular Assist Devices

Effective Date: March 27, 2007

Implementation Date: May 14, 2007

I. GENERAL INFORMATION

A. Background: A ventricular assist device (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 post-cardiotomy, as a bridge to a heart transplant, or as destination therapy. Destination therapy is an indication for patients that are not heart transplant eligible and therefore expect to require use of the VAD through the end of life.

B. Policy: Through a National Coverage Determination (NCD Manual 100-03 §20.9, "Artificial Hearts and Related Devices") issued on October 2003, 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 CMS and if approved, would then be listed on the CMS Web site as an approved VAD destination therapy hospital. At that time contractors were instructed to use that Web site to determine which hospitals in their area were Medicare approved for VADs as destination therapy (Change Request 2958, Issued October 14, 2003). Effective March 27, 2007, new facility criteria is established and hospitals must now receive certification from the Joint Commission on Accreditation of Healthcare Organizations under their Disease Specific Certification Program for VADs. Currently approved hospitals must meet the new facility criteria and will have until March 27, 2009, to become certified by the Joint Commission or they will be removed from the approved list.

The Web site (<http://www.cms.hhs.gov/MedicareApprovedFacilities/VAD/list.asp#TopOfPage>) will be continuously updated to maintain a current list of approved facilities. Contractors shall continue to use this web site to determine which hospitals are covered by Medicare when VADs are implanted as destination therapy.

II. BUSINESS REQUIREMENTS TABLE

Use "Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)													
		A	D	F	C	D	R	H	Shared-System Maintainers	OTHER					
		/	M	I	A	M	E	H	I	F	M	V	C	W	
		B	E	R	R	R	I	C	S	S	S	M	V	C	W
		M	M	I	C	A	E	A	S	S	S	M	V	C	W
		A	A	E	C	C	R	R	S	S	S	M	V	C	W
5516.1	Contractors shall continue to use the following CMS Web site to establish the approval status of hospitals for ventricular assist devices implanted for the destination therapy clinical indication.	X		X	X										
	http://www.cms.hhs.gov/MedicareApprove														

Number	Requirement	Responsibility (place an "X" in each applicable column)											
		A / B	D M E	F I	C A R	D M E	R H H	I	Shared-System Maintainers				OTHER
M A C	M A C	M A C	R I E	R I E	R I C		F I S S	M C S	V M S	C W F			
	dFacilitie/VAD/list.asp#TopOfPage												

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)											
		A / B	D M E	F I	C A R	D M E	R H H	I	Shared-System Maintainers				OTHER
M A C	M A C	M A C	R I E	R I E	R I C		F I S S	M C S	V M S	C W F			
5516.2	A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X		X	X								

IV. SUPPORTING INFORMATION

A. For any recommendations and supporting information associated with listed requirements, use the box below:

Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

B. For all other recommendations and supporting information, use the space below:

V. CONTACTS

Pre-Implementation Contact(s): JoAnna Baldwin, 410.786.7205, joanna.baldwin@cms.hhs.gov

Post-Implementation Contact(s): Regional office

VI. FUNDING

A. TITLE XVIII Contractors:

No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2007 operating budgets.

B. Medicare Administrative Contractors:

The contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the Statement of Work (SOW). The contractor is not obligated to incur costs in excess of the amounts specified in your contract unless and until specifically authorized by the contracting officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the contracting officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

Medicare National Coverage Determinations Manual

Chapter 1, Part 1 (Sections 10 – 80.12) Coverage Determinations

Table of Contents

(Rev. 68, 04-13-07)

20.9 - Artificial Hearts and Related Devices (*Effective March 27, 2007*)

20.9 - Artificial Hearts and Related Devices (*Effective March 27, 2007*)
(*Rev.68, Issued: 04-13-07, Effective: 03-27-07, Implementation: 05-14-07*)

A. General

A ventricular assist device (VAD) or left ventricular assist device (LVAD) is used to assist a damaged or weakened heart in pumping blood. These devices are used for support of blood circulation post-cardiotomy, as a bridge to a heart transplant, or as destination therapy.

B. Nationally Covered Indications

1. Postcardiotomy (effective for services performed on or after October 18, 1993)

Post-cardiotomy is the period following open-heart surgery. VADs used for support of blood circulation post-cardiotomy are covered only if they have received approval from the Food and Drug Administration (FDA) for that purpose, and the VADs are used according to the FDA- approved labeling instructions.

2. Bridge-to-Transplant (effective for services performed on or after January 22, 1996)

The VADs used for bridge-to-transplant are covered only if they have received approval from the FDA for that purpose, and the VADs are used according to the FDA-approved labeling instructions. All of the following criteria must be fulfilled in order for Medicare coverage to be provided for a VAD used as a bridge-to-transplant:

- a. The patient is approved and listed as a candidate for heart transplantation by a Medicare-approved heart transplant center; and
- b. The implanting site, if different than the Medicare-approved transplant center, must receive written permission from the Medicare-approved heart transplant center under which the patient is listed prior to implantation of the VAD.

The Medicare-approved heart transplant center should make every reasonable effort to transplant patients on such devices as soon as medically reasonable. Ideally, the Medicare-approved heart transplant centers should determine patient-specific timetables for transplantation, and should not maintain such patients on VADs if suitable hearts become available.

3. Destination Therapy (effective for services performed on or after October 1, 2003 *with facility criteria updated March 27, 2007*)

Destination therapy is for patients that require permanent mechanical cardiac support. The VADs used for destination therapy are covered only if they have received approval

from the FDA for that purpose, and the device is used according to the FDA-approved labeling instructions.

Patient Selection

The VADs are covered for patients who have chronic end-stage heart failure (New York Heart Association Class IV end-stage left ventricular failure for at least 90 days with a life expectancy of less than 2 years), are not candidates for heart transplantation, and meet all of the following conditions:

- a. The patient's Class IV heart failure symptoms have failed to respond to optimal medical management, including dietary salt restriction, diuretics, digitalis, beta-blockers, and ACE inhibitors (if tolerated) for at least 60 of the last 90 days;
- b. The patient has a left ventricular ejection fraction (LVEF) < 25%;
- c. The patient has demonstrated functional limitation with a peak oxygen consumption of < 12 ml/kg/min; or the patient has a continued need for intravenous inotropic therapy owing to symptomatic hypotension, decreasing renal function, or worsening pulmonary congestion; and,
- d. The patient has the appropriate body size ($\geq 1.5 \text{ m}^2$) to support the VAD implantation.

Facility Criteria

- a. *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;*
- b. *Facilities must be a member of the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS); and*
- c. *By March 27, 2009, all facilities must meet the above facility criteria and be credential by the Joint Commission under the Disease Specific Certification Program for Ventricular Assist Devices (standards dated February 2007).*

The Web site

<http://www.cms.hhs.gov/MedicareApprovedFacilities/VAD/list.asp#TopOfPage> will be updated continuously to list all approved facilities. Facilities gaining Joint Commission certification (including prior to March 27, 2009) will be added to the Web site when certification is obtained.

Hospitals also must have in place staff and procedures that ensure that prospective VAD recipients receive all information necessary to assist them in giving appropriate informed

consent for the procedure so that they and their families are fully aware of the aftercare requirements and potential limitations, as well as benefits, following VAD implantation.

C. *Nationally Non-Covered Indications (effective for services performed on or after May 19, 1986)*

1. Artificial Heart

Since there is no authoritative evidence substantiating the safety and effectiveness of a VAD used as a replacement for the human heart, Medicare does not cover this device when used as an artificial heart.

All other indications for the use of VADs not otherwise listed remain noncovered, except in the context of Category B IDE clinical trials (42 CFR 405) or as a routine cost in clinical trials defined under section 310.1 of the NCD manual (old CIM 30-1).

(This NCD last reviewed March 2007.)