Foreword - Purpose for National Coverage Determinations Manual

A - Purpose

(Rev. 2, 10-17-03)

The statutory and policy framework within which National Coverage Decisions are made may be found in title XVIII of the Social Security Act (the Act), and in Medicare regulations and rulings. The National Coverage Determinations Manual describes whether specific medical items, services, treatment procedures, or technologies can be paid for under Medicare. National coverage decisions have been made on the items addressed in this manual. All decisions that items, services, etc. are not covered are based on §1862(a)(1) of the Act (the "not reasonable and necessary" exclusion) unless otherwise specifically noted. Where another statutory authority for denial is indicated, that is the sole authority for denial. Where an item, service, etc. is stated to be covered, but such coverage is explicitly limited to specified indications or specified circumstances, all limitations on coverage of the items or services because they do not meet those specified indications or circumstances are based on §1862(a)(1) of the Act. Where coverage of an item or service is provided for specified indications or circumstances but is not explicitly excluded for others, or where the item or service is not mentioned at all in the CMS Manual System the Medicare contractor is to make the coverage decision, in consultation with its medical staff, and with CMS when appropriate, based on the law, regulations, rulings and general program instructions

The coverage decisions in the manual will be kept current, based on the most recent medical and other scientific and technical advice available to CMS.

Other manuals in this system in which coverage-related instructions may be found are:

Pub 100-2 (Benefit Policy);
Pub 100-4 (Claims Processing);
Pub 100-5 (Medicare Secondary Payer); and
Pub 100-8 (Program Integrity)

These manuals usually contain more general coverage descriptions and/or processing instructions. There should be no inconsistencies among the instructions in any of these manuals and the National Coverage Determinations Manual. If any such inconsistencies are found, bring them to the attention of CMS, OSORA.

B - Organization

The NCD manual is organized by categories, e.g., Medical Procedures, Supplies, Diagnostic Services. A Table of Contents is provided at the beginning of the manual designating coverage decision categories. Each subject discussed within the category is listed and identified by a number.

The revision transmittal sheet identifies new material and summarizes the principal changes. When a change in policy or procedure is involved, the background and effective date for the change is provided. If, at a later date, the reader wishes to refer to the background explanation given on a transmittal sheet, the reader can identify the transmittal by its number which appears on each manual page.

C - CMS Coverage Web site

The CMS Coverage Web page http://www.cms.hhs.gov/medcov contains information about pending National Coverage Determinations and also provides access to a database of National Coverage Determinations, National Coverage Analyses, and Local Medical review Policies.

20.9 - ARTIFICIAL HEARTS AND RELATED DEVICES

(Rev2, 10-17-03)

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.

A. 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)*

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)*

*Destination therapy is for patients that require permanent mechanical cardiac support. 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. 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 (≥ 1.5 m^2) to support the VAD implantation.*

In addition, the Centers for Medicare & Medicaid Services (CMS) has determined that VAD implantation as destination therapy is reasonable and necessary only when the procedure is performed in a Medicare-approved heart transplant facility that, between January 1, 2001, and September 30, 2003, implanted at least 15 VADs as a bridge-to-transplant or as destination therapy. These devices must have been approved by the FDA for destination therapy or as a bridge-to-transplant, or have been implanted as part of an FDA investigational device exemption (IDE) trial for one of these two indications. VADs implanted for other investigational indications or for support of blood circulation post-cardiotomy do not satisfy the volume requirement for this purpose. Since the relationship between volume and outcomes has not been well-established for VAD use, facilities that have minimal deficiencies in meeting this standard may apply and include a request for an exception based upon additional factors. Some of the factors CMS will consider are geographic location of the center, number of destination procedures performed, and patient outcomes from VAD procedures completed.

Also, this facility must be an active, continuous member of a national, audited registry that requires submission of health data on all VAD destination therapy patients from the

date of implantation throughout the remainder of their lives. This registry must have the ability to accommodate data related to any device approved by the FDA for destination therapy regardless of manufacturer. The registry must also provide such routine reports as may be specified by CMS, and must have standards for data quality and timeliness of data submissions such that hospitals failing to meet them will be removed from membership. CMS believes that the registry sponsored by the International Society for Heart and Lung Transplantation is an example of a registry that meets these characteristics.

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.

CMS plans to develop accreditation standards for facilities that implant VADs and, when implemented, VAD implantation will be considered reasonable and necessary only at accredited facilities.

A list of facilities eligible for Medicare reimbursement for VADs as destination therapy will be maintained on our website and available at www.cms.hhs.gov/coverage/lvadfacility.asp. In order to be placed on this list, facilities must submit a letter to the Director, Coverage and Analysis Group, 7500 Security Blvd, Mailstop C1-09-06, Baltimore, MD 21244. This letter must be received by CMS within 90 days of the issue date on this transmittal. The letter must include the following information:

- *Facility's name and complete address;*
- *Facility's Medicare provider number;*
- *List of all implantations between Jan. 1, 2001, and Sept. 30, 2003, with the following information:*
    - *Date of implantation,*
    - *Indication for implantation (only destination and bridge-to-transplant can be reported; post-cardiotomy VAD implants are not to be included),*
    - *Device name and manufacturer, and,*
    - *Date of device removal and reason (e.g., transplantation, recovery, device malfunction), or date and cause of patient's death;*
- *Point-of-contact for questions with telephone number;*
- *Registry to which patient information will be submitted**; and,***
- *Signature of a senior facility administrative official.*

Facilities not meeting the minimal standards and requesting exception should, in addition to supplying the information above, include the factors that they deem critical in requesting the exception to the standards.

CMS will review the information contained in the above letters. When the review is complete, all necessary information is received, and criteria are met, CMS will include the name of the newly Medicare-approved facility on the CMS web site. No

reimbursement for destination therapy will be made for implantations performed before the date the facility is added to the CMS web site. Each newly approved facility will also receive a formal letter from CMS stating the official approval date it was added to the list.

B. Noncovered 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.

2. 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 October 2003.)