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# Medicare Hospital Manual

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Department of Health &  
Human Services (DHHS)  
Centers for Medicare &  
Medicaid Services (CMS)

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Transmittal 795

Date: DECEMBER 27, 2002

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## CHANGE REQUEST 2481

<u>HEADER SECTION NUMBERS</u>	<u>PAGES TO INSERT</u>	<u>PAGES TO DELETE</u>
416 – 416 (Cont.)	4-185 – 4-186 (2 pp.)	4-185 – 4-186 (2 pp.)

NEW/REVISED MATERIAL--*EFFECTIVE DATE: April 1, 2003*  
*IMPLEMENTATION DATE: April 1, 2003*

Section 416, Heart Transplants, is being updated to reflect the policy regarding the coverage of artificial hearts and ventricular assist devices (VAD) in §65-15 of the Coverage Issues Manual.

## 416. HEART TRANSPLANTS

Cardiac transplantation is covered under Medicare when performed in a facility, which is approved by Medicare as meeting institutional coverage criteria. On April 6, 1987 CMS Ruling 87-1, "Criteria for Medicare Coverage of Heart Transplants" was published in the **Federal Register**. For Medicare coverage purposes, heart transplants are medically reasonable and necessary when performed in facilities that meet certain criteria. If you wish to obtain coverage for your Medicare patients, you must submit an application and documentation, showing your ongoing compliance with each criterion.

A. Effective Dates.--Coverage is effective for discharges October 17, 1986, for facilities which would have qualified and which applied by July 6, 1987. The effective date of coverage for heart transplants performed at facilities applying after July 6, 1987, is the date the facility receives approval as a heart transplant facility.

CMS informs each hospital of its effective date in an approval letter.

B. Artificial Hearts and Related Devices.-- Medicare does not cover the use of artificial hearts, either as a permanent replacement for a human heart or as a temporary life-support system until a human heart becomes available for transplant (often referred to a "bridge to transplant"). Medicare does cover a Ventricular Assist Devices (VAD) when used as a bridge to transplant when specific criteria are met, but does not cover this device when used as an artificial heart. The following criteria must be fulfilled in order for Medicare coverage to be provided for a VAD used as a bridge to transplant. See section 65-15 of the Coverage Issues Manual for further detail. VADs also are used as temporary support systems. Charges for artificial heart ventricular assist devices and related services are reported as noncovered except in the following situations:

1. The VAD must be used in accordance with the FDA approved labeling instructions. This means that the VAD is used as a temporary mechanical circulatory support for approved transplant candidates as a bridge to cardiac transplantation.
2. The patient is approved and listed as a candidate for heart transplantation by a Medicare approved heart transplant center.
3. 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 implementation of the VAD.

C. Drugs.--Effective January 1, 1987, Medicare covers immunosuppressive drugs following a covered transplant in an approved facility. (See §439.)

D. Noncovered Transplant.--Medicare will not cover transplants or retransplants in facilities which have not been approved as meeting the facility criteria. If a beneficiary is admitted for and receives a heart transplant from you, and your facility is not approved, physicians' services, and inpatient services associated with the transplantation procedure are not covered.

If a beneficiary received a heart transplant from you while you were not an approved facility and later requires services as a result of the noncovered transplant, the services are covered when they are reasonable and necessary in all other respects.

- E. Charges for Heart Acquisition Services.--The excising hospital bills the transplant (implant) hospital for applicable services. Do not submit a bill to your intermediary if you are the excising hospital. If you are the transplant hospital, keep an itemized statement that identifies the services rendered, the charges, the person receiving the service (donor/recipient), and whether this person is a potential transplant donor or recipient. These charges are reflected in your heart acquisition cost center and are used in determining your standard charge for acquiring a cadaver's

heart. The standard charge is not a charge representing the acquisition cost of a specific heart; rather, it reflects the average cost associated with each type of heart acquisition. Also, it is an all inclusive charge for all services required in acquisition of a heart, i.e., tissue typing, post-operative evaluation.

F. Approved Heart Transplant Facilities.--The facilities listed below have been approved as Medicare heart transplant facilities. The effective date of the approval for each is shown. If you have any questions, contact your RO. For a complete list of transplant centers, please visit [www.cms.hhs.gov/providers/transplant/default.asp](http://www.cms.hhs.gov/providers/transplant/default.asp).

List of Approved Medicare Heart Transplant Centers

<u>Name &amp; Address</u>	<u>Effective Date</u>
Medical College of Virginia 11th and Marshall Sts. Richmond, VA 23298	October 17, 1986
Stanford University, University Hospital Stanford University Medical Center Stanford, CA 94305	October 17, 1986
University of Minnesota Hospital and Clinic 420 Delaware Street, S.E. Minneapolis, MN 55455	October 17, 1986
University Medical Center at the Arizona Health Sciences Center 1501 N. Campbell Ave. Tucson, AZ 85724	October 17, 1986
The Johns Hopkins Hospital 600 N. Wolfe St. Baltimore, MD 21205	October 17, 1986
Foster G. McGaw Hospital Loyola University Medical Center 2160 South First Av. Maywood, IL 60163	October 17, 1986 (revised date)
Methodist Hospital/Baylor College of Medicine The Methodist Hospital System 6535 Fannin, M.S. 101 Houston, TX 77030	October 17, 1986
Methodist Hospital of Indiana 1701 North Senate Blvd. Indianapolis, IN 46202	October 17, 1986
Presbyterian University Hospital Desoto at O'Hara Sts. Pittsburgh, PA 15213	October 17, 1986