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# Medicare

## Intermediary Manual

### Part 3 - Claims Process

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

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CHANGE REQUEST 2481

**HEADER SECTION NUMBERS**

3613 – 3613 (Cont.)

**PAGES TO INSERT**

6-133 – 6-134 (2 pp.)

**PAGES TO DELETE**

6-133 – 6-134 (2 pp.)

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

Section 3613, Heart Transplants, is being updated to reflect the policy regarding coverage of artificial hearts and ventricular assist devices (VADs) in §65-15 of the Coverage Issues Manual.

**These instructions should be implemented within your current operating budget.**

CMS-Pub. 13-3

- o If the beneficiary lives east of the Mississippi, excluding Minnesota, send the copy to:  
Blue Cross and Blue Shield  
of South Carolina  
Medicare Immunosuppressive Drug Unit  
Pen Claims  
P.O. Box 102401  
Columbia, SC 29224

See §3718.1 for the message about immunosuppressive drug reimbursement to include in the notice.

### 3613. HEART TRANSPLANTS

A. Background.--On April 6, 1987, HCFA 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. Facilities that wish to obtain coverage for their Medicare patients submit an application and documentation showing their initial and ongoing compliance with each criterion.

The facility mails the application to the address below in a manner which provides it with documentation that it was received, e.g., return receipt requested.

Director  
Division of Integrated Delivery Systems  
Centers for Medicare and Medicaid Services  
Mailstop C4-25-02  
7500 Security Blvd.  
Baltimore, MD 21244

If you have any questions concerning the effective or approval dates of your hospitals, contact your RO.

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 Device (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 implantation of the VAD.

ICD-9-CM procedure code 37.66, Implantation of an implantable pulsatile heart assist system, is and will continue to be listed as a noncovered procedure in the Medicare Code Editor (MCE) due to the

stringent conditions that must be met by hospitals in order to receive payment. If this procedure is listed in accordance with the above criteria, payment is appropriate and you are to override the MCE noncovered edit.

C. Drugs.--Medicare covers immunosuppressive drugs up to 1 year following a covered transplant. (See §3660.8.)

D. Noncovered Transplants.--Medicare does 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 a facility that is not approved, neither physician's services nor inpatient services associated with the transplantation procedure are covered. When a beneficiary has received a heart transplant from a hospital (which has not been approved as meeting the facility criteria) and later requires medical and hospital services as a result of the noncovered transplant, the services are covered when they are reasonable and necessary in all other respects.

E. Bill Review Procedures.--Take the following actions to process heart transplant bills. You may accomplish them manually or you may modify your MCE and Grouper interface programs to handle the processing.

F. Change MCE Interface.--The MCE creates an exception for procedure code 375 (heart transplant). Where this procedure code is identified by MCE, check the provider number to determine if the provider is an approved transplant center. Check the effective approval date. If payment is appropriate (i.e., the center is approved and the service is on or after the approval date) override the noncovered OR procedure edit.

G. Grouper.--If the discharge is October 1, 1987 or later, process the bill through Grouper and Pricer. If the discharge is before October 1, 1987, Pricer does not have the proper DRG weight. Assign a weight of 14.9944 and process to payment. Use a 51 day outlier threshold for discharges before October 1, 1987.

H. Handling Heart Transplant Billings From Nonapproved Hospitals.--Where a heart transplant and covered services are provided by a nonapproved hospital, the bill data processed through Grouper and Pricer must exclude transplant procedure codes and related charges. (See §3656.1.)

I. Effective Dates.--Coverage is effective for discharges no earlier than October 17, 1986, for facilities which applied by July 6, 1987.

J. Approved Heart Transplant Facilities.--The facilities listed following subsection K have been approved as Medicare heart transplant facilities. The effective date for each is shown. If you have any questions, contact your RO. For a complete list of transplant centers, visit [www.hcfa.gov/medicare/tranplan.htm](http://www.hcfa.gov/medicare/tranplan.htm).

K. Charges for Heart Acquisition Services.--Applicable services (see §§3178-3178.19) are billed to the transplant (implant) hospital by the excising hospital. A billing form is not submitted from the excising hospital to you. The transplant hospital keeps an itemized statement that identifies the services rendered, the charges, the person receiving the service (donor/recipient), and whether this is a potential transplant donor or recipient. These charges are reflected in the transplant hospital's heart acquisition cost center and are used in determining the hospital's standard charge for acquiring a live donor's heart. The standard charge is not a charge representing the acquisition cost of a specific heart; rather, it is a charge which reflects the average cost associated with each type of heart acquisition. Also, it is an all inclusive charge for all services required in the acquisition of a heart, i.e., tissue typing, post-operative evaluation.