Medicare Coverage Issues Manual

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

Transmittal 165 **Date: DECEMBER 27, 2002**

CHANGE REQUEST 2481

HEADER SECTION NUMBERS	PAGES TO INSERT	PAGES TO DELETE
35-87 – 35-88	2	2

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

Section 35-87, Heart Transplants, is being updated to reflect the policy regarding the coverage of artificial hearts and ventricular assist devices (VAD) in § 65-15 of this manual.

This revision to the Coverage Issues Manual is a national coverage decision (NCD). NCDs are binding on all Medicare carriers, intermediaries, peer review organizations, health maintenance organizations, competitive medical plans, and health care prepayment plans. Under 42 CFR 422.256 (b), an NCD that expands coverage is also binding on a Medicare+Choice Organization. In addition, an administrative law judge may not review an NCD. (See §1869(f)(1)(A)(i) of the Social Security Act.)

These instructions should be implemented within your current operating budget.

DISCLAIMER: The revision date and transmittal number only apply to the redlined material. All other material was previously published in the manual and is only being reprinted.

Effective for services performed on or after July 1, 1999, the implantation of an automatic defibrillator is also a covered service for patients with the following conditions:

1. A documented episode of cardiac arrest due to ventricular fibrillation not due to a transient or reversible cause;

2. Ventricular tachyarrhythmia, either spontaneous or induced, not due to a transient or reversible cause; or,

3. Familial or inherited conditions with a high risk of life-threatening ventricular tachyarrythmias such as long QT syndrome or hypertrophic cardiomyopathy.

35-86 GASTRIC BALLOON FOR TREATMENT OF OBESITY--NOT COVERED.

The gastric balloon is a medical device developed for use as a temporary adjunct to diet and behavior modification to reduce the weight of patients who fail to lose weight with those measures alone. It is inserted into the stomach to reduce the capacity of the stomach and to affect early satiety.

The use of the gastric balloon is not covered under Medicare, since the long term safety and efficacy of the device in the treatment of obesity has not been established.

35-87 HEART TRANSPLANTS--(Effective for services rendered on or after October 17, 1986.)

A. General.--Cardiac transplantation is covered under Medicare when performed in a facility which is approved by Medicare as meeting institutional coverage criteria. (See HCFA Ruling 87-1.)

B. Exceptions.--In certain limited cases, exceptions to the criteria may be warranted if there is justification and if the facility ensures our objectives of safety and efficacy. Under no circumstances will exceptions be made for facilities whose transplant programs have been in existence for less than two years, and applications from consortia will not be approved.

Although consortium arrangements will not be approved for payment of Medicare heart transplants, consideration will be given to applications from heart transplant facilities that consist of more than one hospital where all of the following conditions exist:

o The hospitals are under the common control or have a formal affiliation arrangement with each other under the auspices of an organization such as a university or a legally-constituted medical research institute; and

o The hospitals share resources by routinely using the same personnel or services in their transplant programs. The sharing of resources must be supported by the submission of operative notes or other information that documents the routine use of the same personnel and services in all of the individual hospitals. At a minimum, shared resources means:

- The individual members of the transplant team, consisting of the cardiac transplant surgeons, cardiologists and pathologists, must practice in all the hospitals and it can be documented that they otherwise function as members of the transplant team; and

- The same organ procurement organization, immunology, and tissue-typing services must be used by all the hospitals; and

o The hospitals submit, in the manner required (Kaplan-Meier method) their individual and pooled experience and survival data; and

o The hospitals otherwise meet the remaining Medicare criteria for heart transplant facilities; that is, the criteria regarding patient selection, patient management, program commitment, etc.

C. Pediatric Hospitals.--Cardiac transplantation is covered for Medicare beneficiaries when performed in a pediatric hospital that performs pediatric heart transplants if the hospital submits an application which HCFA approves as documenting that:

o The hospital's pediatric heart transplant program is operated jointly by the hospital and another facility that has been found by HCFA to meet the institutional coverage criteria in HCFA Ruling 87-1;

o The unified program shares the same transplant surgeons and quality assurance program (including oversight committee, patient protocol, and patient selection criteria); and

o The hospital is able to provide the specialized facilities, services, and personnel that are required by pediatric heart transplant patients.

D. Follow-up Care.--Follow-up care required as a result of a covered heart transplant is covered, provided such services are otherwise reasonable and necessary. Follow-up care is also covered for patients who have been discharged from a hospital after receiving a noncovered heart transplant. Coverage for follow-up care would be for items and services that are reasonable and necessary, as determined by Medicare guidelines. (See Intermediary Manual §3101.l4 and Carriers Manual §2300.1.)

E. Immunosuppressive Drugs.--(See Intermediary Manual §3660.8 and Carriers Manual §§2050.5, 4471 and 5249.)

F. Artificial Hearts.--Medicare does not cover the use of artificial hearts 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 as a "bridge to transplant"). Medicare does cover a ventricular assist device (VAD) when used in conjunction with specific criteria listed in CIM §65-15.

35-88 EXTRACORPOREAL PHOTOPHERESIS (Effective for services performed on or after April 8, 1988.)

Extracorporeal photopheresis is a treatment for cutaneous T-cell lymphoma (CTCL), a condition that is generally resistant to chemotherapy and radiotherapy. The treatment begins with the oral administration of the drug methoxsalen. The patient§s blood is then passed through a device that permits exposure of the blood, while it is outside the body (extracorporeal), to ultraviolet A light. The blood is then returned to the patient.

Extracorporeal photopheresis is covered by Medicare only when used in the palliative treatment of the skin manifestations of CTCL that has not responded to other therapy.