Medicare Coverage Issues Manual

Department of Health and Human Services (DHHS)
HEALTH CARE FINANCING ADMINISTRATION (HCFA)

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REFER TO CHANGE REQUEST 1378

HEADER SECTION NUMBERS	PAGES TO INSERT	PAGES TO DELETE
65-14 – 65-15	2 pp.	2 pp.

NEW/REVISED MATERIAL--*EFFECTIVE DATE:* January 1, 2001
***IMPLEMENTATION DATE:* January 1, 2001**

Section 65-15, Artificial Hearts and Related Devices, is updated to allow sites other than Medicare approved heart transplant centers to implant ventricular assist devices (VADs) in patients who are approved and listed as candidates for heart transplant by a Medicare approved heart transplant center. In addition, the implanting site must receive written permission from the Medicare approved heart transplant center under which the patient is listed prior to implantation of the VAD.

This revision to the Coverage Issues Manual is a national coverage decision (NCD) made under §1862 (a)(1) of the Social Security Act. NCDs are binding on all Medicare carriers, intermediaries, peer review organizations, and other contractors. 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 disregard, set aside, or otherwise review an NCD issued under §1862 (a)(1). (See 42 CFR 405.732 and 405.860.)

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 previous published in the manual and is only being reprinted.

65-13 PHRENIC NERVE STIMULATOR

The implantation of a phrenic nerve stimulator is covered for selected patients with partial or complete respiratory insufficiency.

The phrenic nerve stimulator provides electrical stimulation of the patient's phrenic nerve to contract the diaphragm rhythmically and produce breathing in patients who have hypoventilation (a state in which an abnormally low amount of air enters the lungs). The device has been used successfully to treat hypoventilation caused by a variety of conditions, including respiratory paralysis resulting from lesions of the brain stem and cervical spinal cord and chronic pulmonary disease with ventilatory insufficiency. The phrenic nerve stimulator is intended to be an alternative to management of patients with respiratory insufficiency who are dependent upon the usual therapy of intermittent or permanent use of a mechanical ventilator as well as maintenance of a permanent tracheotomy stoma.

However, an implanted phrenic nerve stimulator can be effective only if the patient has an intact phrenic nerve and diaphragm. Moreover, nerve injury may occur during the surgical procedure and if sufficient injury is incurred, the device will not prove useful to the patient. Consequently, it is possible for such a device to be indicated for a patient but, due to injury sustained during implant, fail to assist the patient, resulting in a return to the use of mechanical ventilation.

65-14 COCHLEAR IMPLANTATION

A cochlear implant device is an electronic instrument, part of which is implanted surgically to stimulate auditory nerve fibers, and part of which is worn or carried by the individual to capture, analyze and code sound. Cochlear implant devices are available in single channel and multi-channel models. The purpose of implanting the device is to provide an awareness and identification of sounds and to facilitate communication for persons who are profoundly hearing impaired.

Medicare coverage is provided only for those patients who meet all of the following selection guidelines.

A. General.--

- Diagnosis of bilateral severe-to-profound sensorineural hearing impairment with limited benefit from appropriate hearing (or vibrotactile) aids;

- Cognitive ability to use auditory clues and a willingness to undergo an extended program of rehabilitation;

- Freedom from middle ear infection, an accessible cochlear lumen that is structurally suited to implantation, and freedom from lesions in the auditory nerve and acoustic areas of the central nervous system;

- No contraindications to surgery; and

- The device must be used in accordance withe the FDA-approved labeling.

B. Adults.--Cochlear implants may be covered for adults (over age 18) for prelinguistically, perilinguistically, and postlinguistically deafened adults. Postlinguistically deafened adults must demonstrate test scores of 30 percent or less on sentence recognition scores from tape recorded tests in the patient’s best listening condition.

C. Children.--Cochlear implants may be covered for prelinguistically and postlinguistically deafened children aged 2 through 17. Bilateral profound sensorineural deafness must be demonstrated by the inability to improve on age appropriate closed-set word identification tasks with amplification.

65-15 ARTIFICIAL HEARTS AND RELATED DEVICES

A ventricular assist device (VAD) is used to assist a damaged or weakened heart in pumping blood. VADs are used as either a bridge to a heart transplant or for support of blood circulation postcardiotomy, which is the period following open heart surgery. VADs used for support of blood circulation postcardiotomy 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. 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 of the following criteria must be fulfilled in order for Medicare coverage to be provided for a VAD used as a bridge to transplant:

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 transplantion by a Medicare approved heart transplant center; and

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.

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