Medicare
Coverage Issues Manual

Department of Health and Human Services (DHHS)

HEALTH CARE FINANCING ADMINISTRATION (HCFA)

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CHANGE REQUEST 1085

HEADER SECTION NUMBERS	PAGES TO INSERT	PAGES TO DELETE
35-46 (Cont.) - 35-52	4 pp.	4 pp.

NEW/REVISED MATERIAL--*EFFECTIVE DATE: April 1, 2000*
IMPLEMENTATION DATE: April 1, 2000

Section 35-48, Osteogenic Stimulation, is revised to define nonunion of long bone fractures as existing when fracture healing has ceased for 3 or more months as confirmed by serial radiographs.

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.

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If TENS significantly alleviates pain, it may be considered as primary treatment; if it produces no relief or greater discomfort than the original pain electrical nerve stimulation therapy is ruled out. However, where TENS produces incomplete relief, further evaluation with percutaneous electrical nerve stimulation may be considered to determine whether an implanted peripheral nerve stimulator would provide significant relief from pain. (See §35-46B.)

Usually, the physician or physical therapist providing the services will furnish the equipment necessary for assessment. Where the physician or physical therapist advises the patient to rent the TENS from a supplier during the trial period rather than supplying it himself/herself, program payment may be made for rental of the TENS as well as for the services of the physician or physical therapist who is evaluating its use. However, the combined program payment which is made for the physician's or physical therapist's services and the rental of the stimulator from a supplier should not exceed the amount which would be payable for the total service, including the stimulator, furnished by the physician or physical therapist alone.

B. Percutaneous Electrical Nerve Stimulation (PENS).--This diagnostic procedure which involves stimulation of peripheral nerves by a needle electrode inserted through the skin is performed only in a physician's office, clinic, or hospital outpatient department. Therefore, it is covered only when performed by a physician or incident to physician's service. If pain is effectively controlled by percutaneous stimulation, implantation of electrodes is warranted.

As in the case of TENS (described in subsection A), generally the physician should be able to determine whether the patient is likely to derive a significant therapeutic benefit from continuing use of an implanted nerve stimulator within a trial period of 1 month. In a few cases, this determination may take longer to make. The medical necessity for such diagnostic services which are furnished beyond the first month must be documented.

NOTE: Electrical nerve stimulators do not prevent pain but only alleviate pain as it occurs. A patient can be taught how to employ the stimulator, and once this is done, can use it safely and effectively without direct physician supervision. Consequently, it is inappropriate for a patient to visit his/her physician, physical therapist, or an outpatient clinic on a continuing basis for treatment of pain with electrical nerve stimulation. Once it is determined that electrical nerve stimulation should be continued as therapy and the patient has been trained to use the stimulator, it is expected that a stimulator will be implanted or the patient will employ the TENS on a continual basis in his/her home. Electrical nerve stimulation treatments furnished by a physician in his/her office, by a physical therapist or outpatient clinic are excluded from coverage by §1862(a)(1) of the Act. (See §65-8 for an explanation of coverage of the therapeutic use of implanted peripheral nerve stimulators under the prosthetic devices benefit. See §60-20 for an explanation of coverage of the therapeutic use of TENS under the durable medical equipment benefit.)

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35-47 BREAST RECONSTRUCTION FOLLOWING MASTECTOMY (Effective for services performed on and after May 15, l980.)

During recent years, there has been a considerable change in the treatment of diseases of the breast such as fibrocystic disease and cancer. While extirpation of the disease remains of primary importance, the quality of life following initial treatment is increasingly recognized as of great concern. The increased use of breast reconstruction procedures is due to several factors:

- o A change in epidemiology of breast cancer, including an apparent increase in incidence;
- o Improved surgical skills and techniques;
- o The continuing development of better prostheses; and
- o Increasing awareness by physicians of the importance of postsurgical psychological adjustment.

Reconstruction of the affected and the contralateral unaffected breast following a medically necessary mastectomy is considered a relatively safe and effective noncosmetic procedure. Accordingly, program payment may be made for breast reconstruction surgery following removal of a breast for any medical reason.

Program payment may not be made for breast reconstruction for cosmetic reasons. (Cosmetic surgery is excluded from coverage under §l862(a)(l0) of the Social Security Act.)

35-48 OSTEOGENIC STIMULATION

Electrical stimulation to augment bone repair can be attained either invasively or noninvasively. Invasive devices provide electrical stimulation directly at the fracture site either through percutaneously placed cathodes or by implantation of a coiled cathode wire into the fracture site. The power pack for the latter device is implanted into soft tissue near the fracture site and subcutaneously connected to the cathode, creating a self-contained system with no external components. The power supply for the former device is externally placed and the leads connected to the inserted cathodes. With the noninvasive device, opposing pads, wired to an external power supply, are placed over the cast. An electromagnetic field is created between the pads at the fracture site.

1. Noninvasive Stimulator.--The noninvasive stimulator device is covered only for the following indications:

- o Nonunion of long bone fractures;
- o Failed fusion, where a minimum of nine months has elapsed since the last surgery;
- o Congenital pseudarthroses; and
- o As an adjunct to spinal fusion surgery for patients at high risk of pseudarthrosis due to previously failed spinal fusion at the same site or for those undergoing multiple level fusion. A multiple level fusion involves 3 or more vertebrae (e.g., L3-L5, L4-S1, etc).

2. Invasive (Implantable) Stimulator.--The invasive stimulator device is covered only for the following indications:

- o Nonunion of long bone fractures; and
- o As an adjunct to spinal fusion surgery for patients at high risk of pseudarthrosis due to previously failed spinal fusion at the same site or for those undergoing multiple level fusion. A multiple level fusion involves 3 or more vertebrae (e.g., L3-L5, L4-S1, etc).

Effective for services performed on or after September 15, 1980, nonunion of long bone fractures, for both noninvasive and invasive devices, is considered to exist only after six or more months have elapsed without healing of the fracture.

Effective for services performed on or after April 1, 2000, nonunion of long bone fractures, for both noninvasive and invasive devices, is considered to exist only when serial radiographs have confirmed that fracture healing has ceased for three or more months prior to starting treatment with the electrical osteogenic stimulator. Serial radiographs must include a minimum of two sets of radiographs, each including multiple views of the fracture site, separated by a minimum of 90 days.

B. Ultrasonic Osteogenic Stimulators.--An ultrasonic osteogenic stimulator is a non-invasive device that emits low intensity, pulsed ultrasound. The ultrasound signal is applied to the skin surface at the fracture location via ultrasound, conductive, coupling gel in order to accelerate the healing time of the fracture. The device is intended for use with cast immobilization.

There is insufficient evidence to support the medical necessity of using an ultrasonic osteogenic stimulator. Therefore, the device is not covered, because it is not considered reasonable and necessary.

35-49 HYPERTHERMIA FOR TREATMENT OF CANCER (Effective for services performed on or after December 31, 1984.)

Local hyperthermia for treatment of cancer consists of the use of heat to make tumors more susceptible to cancer therapy measures.

Local hyperthermia is covered under Medicare when used in connection with radiation therapy for the treatment of primary or metastatic cutaneous or subcutaneous superficial malignancies. It is not covered when used alone or in connection with chemotherapy.

35-50 COCHLEOSTOMY WITH NEUROVASCULAR TRANSPLANT FOR MENIERE'S DISEASE - NOT COVERED

Meniere's disease (or syndrome) is a common cause of paroxysmal vertigo. Meniere's syndrome is usually treated medically. When medical treatment fails, surgical treatment may be required.

While there are two recognized surgical procedures used in treating Meniere's disease (decompression of the endolymphatic hydrops and labyrinthectomy), there is no scientific evidence supporting the safety and effectiveness of cochleostomy with neurovascular transplant in treatment of Meniere's syndrome. Accordingly, Medicare does not cover cochleostomy with neurovascular transplant for treatment of Meniere's disease.

35-51 HEMODIALYSIS FOR TREATMENT OF SCHIZOPHRENIA - NOT COVERED

Scientific evidence supporting use of hemodialysis as a safe and effective means of treatment for schizophrenia is inconclusive at this time. Accordingly, Medicare does not cover hemodialysis for treatment of schizophrenia.

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35-52 LASER PROCEDURES

Medicare recognizes the use of lasers for many medical indications. Procedures performed with lasers are sometimes used in place of more conventional techniques. In the absence of a specific noncoverage instruction, and where a laser has been approved for marketing by the Food and Drug Administration, contractor discretion may be used to determine whether a procedure performed with a laser is reasonable and necessary and, therefore, covered.

The determination of coverage for a procedure performed using a laser is made on the basis that the use of lasers to alter, revise, or destroy tissue is a surgical procedure. Therefore, coverage of laser procedures is restricted to practitioners with training in the surgical management of the disease or condition being treated.

35-53 ADULT LIVER TRANSPLANTATION

A. General.--Effective July 15, 1996, adult liver transplantation when performed on beneficiaries with end stage liver disease other than hepatitis B or malignancies is covered under Medicare when performed in a facility which is approved by HCFA as meeting institutional coverage criteria.

Effective December 10, 1999, adult liver transplantation when performed on beneficiaries with end stage liver disease other than malignancies is covered under Medicare when performed in a facility which is approved by HCFA as meeting institutional coverage criteria.

Coverage of adult liver transplantation is effective as of the date of the facility's approval, but for applications received before July 13, 1991, can be effective as early as March 8, 1990. (See Federal Register 56 FR 15006 dated April 12, 1991.)

B. Follow-up Care.--Follow-up care or retransplantation (ICD-9-CM 996.82, Complications of Transplanted Organ, Liver) required as a result of a covered liver 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 liver transplant. Coverage for follow-up care is for items and services that are reasonable and necessary as determined by Medicare guidelines. (See Intermediary Manual, §3101.14 and Carriers Manual, §2300.1.)

C. Immunosuppressive Drugs.--See Intermediary Manual, §3660.8 and Carriers Manual, §§2050.5, 4471, and 5249.

35-53.1 PEDIATRIC LIVER TRANSPLANTATION

Effective for services performed on or after February 9, 1984, liver transplantation is covered for children (under age 18) with extrahepatic biliary atresia or any other form of end stage liver disease, except that coverage is not provided for children with a malignancy extending beyond the margins of the liver or those with persistent viremia.

Effective for services performed on or after April 12, 1991, liver transplantation is covered for Medicare beneficiaries when performed in a pediatric hospital that performs pediatric liver transplants if the hospital submits an application which HCFA approves documenting that:

- The hospital's pediatric liver transplant program is operated jointly by the hospital and another facility that has been found by HCFA to meet the institutional coverage criteria in the Federal Register notice of April 12, 1991;

- The unified program shares the same transplant surgeons and quality assurance program

(including oversight committee, patient protocol, and patient selection criteria); and