CHANGE REQUEST 2313

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

Section 35-98 Electrical Stimulation for the Treatment of Wounds, pursuant to court's decision Aitken v Shalala, the court ordered an injunction to the national non-coverage policy on the use of electrical stimulation for the treatment of wounds.

The court has enjoined CMS and its agents from enforcing or giving effect to the Coverage Issues Manual §35-98. The court's preliminary injunction continues to be in effect. Therefore, continue to adjudicate all claims for electrical stimulation without regard to the national policy, described in CIM§35-98. This includes all claims for services performed after July 14, 1997. A new policy on electrical stimulation for the treatment of wounds can be found in CIM §35-102 and will be effective for claims with dates of service on or after April 1, 2003. We will delete the outdated reference from the CIM as soon as the court injunction has been lifted.

Section 35-102 Electrical Stimulation for the Treatment of Wounds, electrical stimulation for the treatment of wounds is the application of electrical current through electrodes placed directly on the skin in close proximity to the wound. Based on evidence that we have reviewed, we are issuing a coverage decision on the use of electrical stimulation only for chronic Stage III and Stage IV pressure ulcers, arterial ulcers, diabetic ulcers and venous stasis ulcers. Electrical stimulation will not be covered as an initial treatment modality. The use of electrical stimulation will be covered only after standard wound therapy has been tried for at least 30-days and there are no measurable signs of healing. Medicare will not cover any form of electromagnetic therapy for the treatment of chronic wounds.

Section 60-9 Durable Medical Equipment - Reference List, electrical stimulation for the treatment of wounds Unsupervised home use of electrical stimulation for wounds will not be covered, as unsupervised home use has not been found to be medically reasonable and necessary.

This revision to the Coverage Issues Manual is a national coverage decision (NCD). NCDs are binding on all carriers, intermediaries, peer review organization, 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.**

Supplies - Drugs

Diagnostic Services

SALVAGE CRYOSURGERY OF PROSTATE AFTER RADIATION FAILURE (Effective for services performed after July 1, 2001.) Salvage cryosurgery of the prostate for recurrent cancer is medically necessary and appropriate only for those patients with localized disease who:

1. Have failed a trial of radiation therapy as their primary treatment; and

2. Meet one of the following conditions: Stage T2B or below, Gleason score < 9, PSA < 8 ng/mL.

Cryosurgery as salvage therapy is therefore not covered under Medicare after failure of other therapies as the primary treatment. Cryosurgery as salvage is only covered after the failure of a trial of radiation therapy, under the conditions noted above.

35-97 VERTEBRAL AXIAL DECOMPRESSION (VAX-D) - NOT COVERED

Vertebral axial decompression is performed for symptomatic relief of pain associated with lumbar disk problems. The treatment combines pelvic and/or cervical traction connected to a special table that permits the traction application. There is insufficient scientific data to support the benefits of this technique. Therefore, VAX-D is not covered by Medicare.

35-98 ELECTRICAL STIMULATION FOR THE TREATMENT OF WOUNDS

Electrical stimulation (ES) has been used or studied for many different applications, one of which is accelerating wound healing. The types of ES used for healing chronic venous and arterial wound and pressure ulcers are direct current (DC), alternating current (AC), pulsed current (PC), pulsed electromagnetic induction (PEMI), and spinal cord stimulation (SCS). An example of AC is transcutaneous electrical stimulation (TENS). The PEMI includes Pulsed Electromagnetic Field (PEMF) and Pulsed Electromagnetic Energy (PEE) using pulsed radio frequency energy, both of which are nonthermal i.e., they do not produce heat. Some ES use generators to create energy in the means such as coils, rather than by leads or surface electrodes.

There is insufficient evidence to determine any clinically significant differences in healing rates. Therefore, ES cannot be covered by Medicare because its effectiveness has not been adequately demonstrated.

35-99 ABORTION

Abortions are not covered Medicare procedures except:

1. If the pregnancy is the result of an act of rape or incest; or

2. In the case where a woman suffers from a physical disorder, physical injury, or physical illness, including a life-endangering physical condition caused by or arising from the pregnancy itself, that would, as certified by a physician, place the woman in danger of death unless an abortion is performed.

This restricted coverage applies to CPT codes 59840, 59841, 59850, 59851, 59852, 59855, 59856, 59857, and 59866.

35-100 PHOTODYNAMIC THERAPY

Photodynamic therapy is a medical procedure which involves the infusion of a photosensitive (light-activated) drug with a very specific absorption peak. This drug is chemically designed to have a unique affinity for the diseased tissue intended for treatment. Once introduced to the body, the drug

accumulates and is retained in diseased tissue to a greater degree than in normal tissue. Infusion is followed by the targeted irradiation of this tissue with a non-thermal laser, calibrated to emit light at a wavelength that corresponds to the drug's absorption peak. The drug then becomes active and locally treats the diseased tissue.

Ocular photodynamic therapy (OPT)

OPT is used in the treatment of ophthalmologic diseases. OPT is only covered when used in conjunction with verteporfin (see §45-30 PHOTOSENSITIVE DRUGS).

A. Classic Subfoveal Choroidal Neovascular (CNV) Lesions.--OPT is covered with a diagnosis of neovascular age-related macular degeneration (AMD) with predominately classic subfoveal choroidal neovascular (CNV) lesions (where the area of classic CNV occupies ≥ 50% of the area of the entire lesion) at the initial visit as determined by a fluorescein angiogram. Subsequent follow-up visits will require a fluorescein angiogram prior to treatment. There are no requirements regarding visual acuity, lesion size, and number of re-treatments.

B. Occult Subfoveal Choroidal Neovascular (CNV) Lesions.--OPT is noncovered for patients with a diagnosis of age-related macular degeneration (AMD*)* with occult and no classic CNV lesions.

C. Other Conditions.--Use of OPT with verteporfin for other types of AMD (e.g., patients with minimally classic CNV lesions, atrophic, or dry AMD) is noncovered. OPT with verteporfin for other ocular indications such as pathologic myopia or presumed ocular histoplasmosis syndrome, is eligible for coverage through individual contractor discretion.

35-101 TREATMENT OF ACTINIC KERATOSIS (Effective for services performed on and after (November 26, 2001.)

Actinic keratoses (AKs), also known as solar keratoses, are common, sun-induced skin lesions that are confined to the epidermis and have the potential to become a skin cancer.

Various options exist for treating AKs. Clinicians should select an appropriate treatment based on the patient's medical history, the lesion's characteristics, and on the patient's preference for a specific treatment. Commonly performed treatments for AKs include cryosurgery with liquid nitrogen, topical drug therapy, and curettage. Less commonly performed treatments for AK include dermabrasion, excision, chemical peels, laser therapy, and photodynamic therapy (PDT). An alternative approach to treating AKs is to observe the lesions over time and remove them only if they exhibit specific clinical features suggesting possible transformation to invasive squamous cell carcinoma (SCC).

Medicare covers the destruction of actinic keratoses without restrictions based on lesion or patient characteristics.

35-102 ELECTRICAL STIMULATION FOR THE TREATMENT OF WOUNDS (Effective for services on and after April 1, 2003)

Electrical stimulation (ES) has been used or studied for many different applications, one of which is accelerating wound healing. Electrical stimulation for the treatment of wounds is the application of electrical current through electrodes placed directly on the skin in close proximity to the wound. Electrical stimulation for the treatment of wounds will only be covered for chronic Stage III or Stage IV pressure ulcers, arterial ulcers, diabetic ulcers and venous stasis ulcers. All other uses of electrical stimulation for the treatment of wounds are noncovered. Chronic ulcers are defined as ulcers that have not healed within 30 days of occurrence. Electrical stimulation will not be covered as an initial treatment modality.

The use of electrical stimulation for the treatment of wounds is considered an adjunctive therapy. Electrical stimulation will be covered only after appropriate standard wound therapy has been tried for at least 30-days and there are no measurable signs of healing. This 30-day period can begin while the wound is acute. Measurable signs of improved healing include a decrease in wound size, either surface area or volume, decrease in amount of exudates and decrease in amount of necrotic tissue. Standard wound care includes: optimization of nutritional status; debridement by any means to remove devitalized tissue; maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings; and necessary treatment to resolve any infection that may be present. Standard wound care based on the specific type of wound includes: frequent repositioning of a patient with pressure ulcers (usually every 2 hours); off-loading of pressure and good glucose control for diabetic ulcers; establishment of adequate circulation for arterial ulcers; and the use of a compression system for patients with venous ulcers.

Continued treatment with electrical stimulation is not covered if measurable signs of healing have not been demonstrated within any 30-day period of treatment. Electrical stimulation must be discontinued when the wound demonstrates 100 per-cent epithelialzed wound bed.

Any form of electromagnetic therapy for the treatment of chronic wounds will not be covered.

This service can only be covered when performed by a physician, physical therapist, or incident to a physician service. Evaluation of the wound is an integral part of wound therapy. When a physician, physical therapist, or a clinician incident to a physician, performs electrical stimulation, that practitioner must evaluate the wound and contact the treating physician if the wound worsens. If electrical stimulation is being used, wounds must be evaluated at least monthly by the treating physician.

Unsupervised use of electrical stimulation for wound therapy will not be covered, as this use has not been found to be medically reasonable and necessary.

would not be a factor in this determination. However, confinement of a patient to his home in a case where there are no toilet facilities in the home may be equated to room confinement. Moreover, payment may also be made if a patient's medical condition confines him to a floor of his home and there is no bathroom located on that floor (See hospital beds in §60-18 for definition of "bed confinement".)

Communicator --(See §60-23, Speech Generating Devices)

Continuous Passive Motion --Continuous passive motion devices are devices covered for patients who have received a total knee replacement. To qualify for coverage, use of the device must commence within 2 days following surgery. In addition, coverage is limited to that portion of the three week period following surgery during which the device is used in the patient's home.

There is insufficient evidence to justify coverage of these devices for longer periods of time or for other applications.

Continuous Positive Airway Pressure (CPAP) --(See §60-17.)

Crutches --covered if patient's condition impairs Ambulation

Cushion Lift Power Seat--(See Seat Lifts.)

Dehumidifiers (room or central heating system type) --deny--environmental control equipment; not primarily medical in nature (§l861(n) of the Act

Diathermy Machines (standard pulses wave types)	--deny--inappropriate for home use (See and §35-41.)
Digital Electronic Pacemaker Monitor	--(See Self-Contained Pacemaker Monitor.)
Disposable Sheets and Bags	--deny--nonreusable disposable supplies (§1861(n) of the Act)
Elastic Stockings	--deny--nonreusable supply; not rental-type items (§1861(n) of the Act)
Electric Air Cleaners	--deny--(See Air Cleaners.) (§1861(n) of the Act)
Electric Hospital Beds	--(See Hospital Beds §60-18.)
Electrical Stimulation for Wounds	--deny--inappropriate for home use
Electrostatic Machines	--deny--(See Air Cleaners and Air Conditioners.) (§1861(n) of the Act)
Elevators	--deny--convenience item; not primarily medical in nature (§1861(n) of the Act)
Emesis Basins	--deny--convenience item; not primarily medical in nature (§1861(n) of the Act)
Esophageal Dilator	--deny--physician instrument; inappropriate for patient use
Exercise Equipment	--deny--not primarily medical in nature (§1861(n) of the Act)
Fabric Supports	--deny--nonreusable supplies; not rental-type it (§1861(n) of the Act)
Face Masks (oxygen)	--covered if oxygen is covered (See § 60-4.)
Face Masks (surgical)	--deny--nonreusable disposable items (§1861(n) of the Act)