Medicare Coverage Issues Manual	Department of Health & Human Services (DHHS) Centers for Medicare & Medicaid Services (CMS)
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**CHANGE REQUEST 1892** 

HEADER SECTION NUMBERS<br/>Table of ContentsPAGES TO INSERT<br/>2 pp.PAGES TO DELETE<br/>2 pp.35-97 - 35-1012 pp.2 pp.

#### NEW/REVISED MATERIAL--EFFECTIVE DATE: November 26, 2001 IMPLEMENTATION DATE: November 26, 2001

<u>Section 35-101, Treatment of Actinic Keratosis (AK)</u>, permits coverage for the destruction of actinic keratoses. Coverage is extended for surgical or medical treatment methods, including but not limited to cryosurgery with liquid nitrogen, curettage, excision, and photodynamic therapy (PDT), without restrictions based on patient or lesion characteristics. Medicare contractors retain discretion to determine the number of visits considered reasonable and necessary to treat these lesions.

This revision to the Coverage Issues Manual (CIM) 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 review an NCD. (See §1869 (f)(1)(A)(i)).

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.

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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 ELECTROSTIMULATION IN THE TREATMENT OF WOUNDS - NOT COVERED

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 radio frequency band, delivered in megahertz (MHz). They typically deliver energy by contacting 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. Effective July 1, 2001, OPT (CPT code 67221) is only covered when used in conjunction with verteporfin (see §45-30 PHOTOSENSITIVE DRUGS). For patients with age-related macular degeneration, OPT is only covered with a diagnosis of neovascular age-related macular degeneration (ICD-9-CM 362.52) 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 (CPT code 92235). Subsequent follow-up visits will require a fluorescein angiogram prior to treatment. There are no requirements regarding visual acuity, lesion size, and number of retreatments.

# 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.