
Medicare Coverage Issues Manual

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

Transmittal 135

Date: FEBRUARY 26, 2001

CHANGE REQUEST 1549

<u>HEADER SECTION NUMBERS</u>	<u>PAGES TO INSERT</u>	<u>PAGES TO DELETE</u>
Table of Contents	2 pp.	2 pp.
35-100 – 35-100 (Cont.)	2 pp.	1 p.
45-30 – 45-30	1 p.	1 p.

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

Section 35-100, Photodynamic Therapy, is added to include ocular photodynamic therapy (OPT), when used in conjunction with verteporfin, for patients with 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), as determined by a fluorescein angiogram.

Section 45-30, Photosensitive Drugs, is added to include verteporfin for use in OPT for patients with neovascular AMD with predominately classic subfoveal CNV lesions (where the area of classic CNV occupies = 50% of the area of the entire lesion), as determined by a fluorescein angiogram.

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.

This section of the Medicare Coverage Issues Manual is a national coverage decision made under §1862(a)(1) of the Social Security Act (the Act). National coverage determinations 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 a national coverage decision issued under §1862(a)(1). 42 CFR §§ 405.732, 405.860.

COVERAGE ISSUES

Nonselective (Random) Transfusions and Living-Related Donor Specific Transfusions (DST) in Kidney Transplantation	35-71
Electrotherapy for Treatment of Facial Nerve Paralysis (Bell's Palsy) - Not Covered	35-72
Injection Sclerotherapy for Esophageal Variceal Bleeding	35-73
External Counterpulsation (ECP) for Severe Angina	35-74
Intraoperative Ventricular Mapping	35-75
Neuromuscular Electrical Stimulation (NMES) in the Treatment of Disuse Atrophy	35-77
Diagnostic Endocardial Electrical Stimulation (Pacing)	35-78
Anesthesia in Cardiac Pacemaker Surgery	35-79
Treatment of Kidney Stones	35-81
Pancreas Transplants	35-82
24-Hour Ambulatory Esophageal pH Monitoring	35-83
Stereotactic Cingulotomy as a Means of Psychosurgery - Not Covered	35-84
Implantation of Automatic Defibrillators	35-85
Gastric Balloon for Treatment of Obesity - Not Covered	35-86
Heart Transplants	35-87
Extracorporeal Photopheresis	35-88
Speech Pathology Services for the Treatment of Dysphagia	35-89
Extracorporeal Immunoabsorption (ECI) Using Protein A Columns for the Treatment of Patients With Idiopathic Thrombocytopenia Purpura (ITP) Failing Other Treatments	35-90
Laparoscopic Cholecystectomy	35-91
Transcendental Meditation--Not Covered	35-92
Lung Volume Reduction Surgery (Reduction Pneumoplasty, Also Called Lung Shaving or Lung Contouring) Unilateral or Bilateral By Open or Thoracoscopic Approach for Treatment of Emphysema and Chronic Obstructive Pulmonary Disease - Not Covered	35-93
Transmyocardial Revascularization With Laser - Not Covered	35-94
Partial Ventriculectomy (Also known as Ventricular Reduction, Ventricular Remodeling, or Heart Volume Reduction Surgery) - Not Covered	35-95
Cryosurgery of Prostate - Not Covered	35-96
Vertebral Axial Decompression (VAX-D) - Not Covered	35-97
Electronicstimulation in the Treatment of Wounds	35-98
Abortion	35-99
Photodynamic Therapy	35-100

Supplies - Drugs

L-Dopa	45-1
Insulin Syringe	45-3
Vitamin B-12 Injections to Strengthen Tendons, Ligaments, Etc., of the Foot - Not Covered	45-4
Hydrophilic Contact Lens for Corneal Bandage	45-7
Laetrile and Related Substances - Not Covered	45-10
Autogenous Epidural Blood Graft	45-11
Porcine Skin and Gradient Pressure Dressing	45-12
Physician's Office Within an Institution - Coverage of Services and Supplies Incident to a Physician's Services	45-15
Certain Drugs Distributed by the National Cancer Institute	45-16
Transfer Factor for Treatment of Multiple Sclerosis Granulocyte Transfusions	45-18
Transcutaneous Electrical Nerve Stimulation (TENS) for Acute Post-Operative Pain	45-19

COVERAGE ISSUES

Ethylenediamine-Tetra-Acetic (EDTA) Chelation Therapy for Treatment of Atherosclerosis	45-20
Scalp Hypothermia During Chemotherapy to Prevent Hair Loss	45-21
Lymphocyte Immune Globulin, Anti- Thymocyte Globulin (Equine)	45-22
Dimethyl Sulfoxide (DMSO)	45-23
Anti-Inhibitor Coagulant Complex (AICC)	45-24
Supplies Used in the Delivery of Transcutaneous Electrical Nerve Stimulation (TENS) and Neuromuscular Electrical Stimulation (NMES)	45-25
Platelet-Derived Wound Healing Formula	45-26
Blood Transfusions	45-27
Antigens Prepared for Sublingual Administration	45-28
Intravenous Iron Therapy	45-29
Photosensitive Drugs	45-30

Diagnostic Services

Cardiac Pacemaker Evaluation Services	50-1
Cytotoxic Food Tests - Not Covered	50-2
His Bundle Study	50-3
Gravlee Jet Washer	50-4
Thermography	50-5
Plethysmography	50-6
Ultrasound Diagnostic Procedures	50-7
Consultation Services Rendered by a Podiatrist in a Skilled Nursing Facility	50-8
Gastrophotography	50-9
Vabra Aspirator	50-10
Computerized Tomography	50-12
Magnetic Resonance Imaging	50-13
Magnetic Resonance Angiography	50-14
Electrocardiographic Services	50-15
Hemorheograph	50-16
Laboratory Tests - CRD Patients	50-17
Electron Microscope	50-18
Pronouncement of Death	50-19
Diagnostic Pap Smears	50-20
Screening Pap Smears and Pelvic Examinations for Early Detection of Cervical Cancer or Vaginal Cancer	50-20.1
Mammograms	50-21
Challenge Ingestion Food Testing	50-22
Histocompatibility Testing	50-23
Hair Analysis	50-24
Esophageal Manometry	50-25
Dental Examination Prior to Kidney Transplantation	50-26
Xenon Scan	50-27
Hospital and Skilled Nursing Facility Admission Diagnostic Procedures	50-28
Cytogenetic Studies	50-29
Nuclear Radiology Procedure	50-30
Evoked Response Tests	50-31
Percutaneous Transluminal Angioplasty (PTA)	50-32
Uroflowmetric Evaluations	50-33
Obsolete or Unreliable Diagnostic Tests	50-34
Sweat Test	50-35
Positron Emission Transverse Tomography (PET or PETT) Scans	50-36
Noninvasive Tests of Carotid Function	50-37

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 PHOTSENSITIVE 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.

45-28 ANTIGENS PREPARED FOR SUBLINGUAL ADMINISTRATION

For antigens provided to patients on or after November 17, 1996, Medicare does not cover such antigens if they are to be administered sublingually, i.e., by placing drops under the patient's tongue. This kind of allergy therapy has not been proven to be safe and effective. Antigens are covered only if they are administered by injection.

45-29 INTRAVENOUS IRON THERAPY (effective for services performed on or after 12/01/00)

Iron deficiency is a common condition in end stage renal disease (ESRD) patients undergoing hemodialysis. Iron is a critical structural component of hemoglobin, a key protein found in normal red blood cells (RBCs) which transports oxygen. Without this important building block, anemic patients experience difficulty in restoring adequate, healthy RBCs that improve hemocrit levels. Clinical management of iron deficiency involves treating patients with iron replacement products while they undergo hemodialysis. Body iron stores can be supplemented with either oral or intravenous (IV) iron products.

The evidence suggests that there is little to distinguish various forms of IV iron therapy in terms of effectiveness. Rather, the medical literature indicates that the mode of intravenous administration is perhaps the most effective treatment for iron deficiency in hemodialysis patients. Unlike oral iron products which must be absorbed through the GI tract, IV iron products are infused directly into the bloodstream in a form that is readily available to the bone marrow for RBC synthesis, resulting in an earlier correction of iron deficiency and anemia. Review of medical literature indicated that the distinction among IV iron products lies within their safety profiles. The IV iron dextran products are associated with a small incidence of severe, life-threatening anaphylaxis. These type I hypersensitivity reactions, which are not dose-related, are immunoglobulin (Ig) E-mediated and are apparently exclusively associated with the dextran forms of injectable iron. In fact, clinical evidence indicates that the dextran component itself is what triggers the severe, life-threatening anaphylactic reactions. *Sodium ferric gluconate complex in sucrose injection* has demonstrated no life-threatening anaphylaxis and a less severe adverse-reaction rate when compared to iron dextran products. Therefore, effective December 1, 2000, Medicare covers *sodium ferric gluconate complex in sucrose injection* when used as a first line treatment of iron deficiency anemia in patients undergoing chronic hemodialysis who are receiving supplemental erythropoietin therapy.

45-30 PHOTSENSITIVE DRUGS

Photosensitive drugs are the light-sensitive agents used in photodynamic therapy. Once introduced into the body, these drugs selectively identify and adhere to diseased tissue. The drugs remain inactive until they are exposed to a specific wavelength of light, by means of a laser, that corresponds to their absorption peak. The activation of a photosensitive drug results in a photochemical reaction which treats the diseased tissue without affecting surrounding normal tissue.

Verteporfin

Verteporfin, a benzoporphyrin derivative, is an intravenous lipophilic photosensitive drug with an absorption peak of 690 nm. This drug was first approved by the Food and Drug Administration (FDA) on April 12, 2000, and subsequently, approved for inclusion in the United States Pharmacopoeia on July 18, 2000, meeting Medicare's definition of a drug as defined under §1861(t)(1) of the Social Security Act. Effective July 1, 2001, Verteporfin (Q3013 – Injection, Verteporfin, 15 mg) is only covered when used in conjunction with ocular photodynamic therapy (see §35-100 PHOTODYNAMIC THERAPY) when furnished intravenously incident to a physician's service. For patients with age-related macular degeneration, Verteporfin 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.