Medicare Coverage Issues Manual

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

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CHANGE REQUEST 1682

HEADER SECTION NUMBERS	PAGES TO INSERT	PAGES TO DELETE
45-30	1 p.	1 p.

NEW/REVISED MATERIAL--*EFFECTIVE DATE: 10/01/01*
IMPLEMENTATION DATE:10/01/01

Section 45-29, Intravenous Iron Therapy, is revised to add *iron sucrose injection* for first line treatment of iron deficiency anemia in patients undergoing chronic hemodialysis who are receiving supplemental erythropoeitin therapy**.**

Until a more specific HCPCS is assigned, use J3490 to bill for *iron sucrose injection*. *Sodium ferric gluconate complex in sucrose injection* should be billed using J2915.

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.

These instructions should be implemented within your current operating budget.

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.

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

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 hematocrit 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 available evidence suggests 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.

A. Effective December 1, 2000, Medicare covers *sodium ferric gluconate complex in sucrose injection* as a first line treatment of iron deficiency anemia when furnished intravenously to patients undergoing chronic hemodialysis who are receiving supplemental erythropoeitin therapy.

B. Effective October 1, 2001, Medicare also covers *iron sucrose injection* as a first line treatment of iron deficiency anemia when furnished intravenously to patients undergoing chronic hemodialysis who are receiving supplemental erythropoeitin therapy.

45-30 PHOTOSENSITIVE 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.