Medicare Coverage Issues Manual

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

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CHANGE REQUEST 2438

HEADER SECTION NUMBERS	PAGES TO INSERT	PAGES TO DELETE
Table of Contents	2 pp	2 pp
45-30 – 45-32 (Cont.)	3 pp	2 pp

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

Section 45-30 Photosensitive Drugs, is revised to delete the code reference for photosensitive drugs in the CIM because it belongs in the claims processing instructions.

Section 45-32 Levocarnitine for Use in the Treatment of Carnitine Deficiency in ESRD Patients, implements the National Coverage Determination (NCD) for Levocarnitine for End Stage Renal Disease under §1862(a)(1)(A) of the Social Security Act.

This section of the Coverage Issues Manual is a National Coverage Determination (NCD) under §1862(a)(1)(A) of the Social Security Act (the Act). NCDs are binding on all Medicare carriers, intermediaries, peer review organizations, 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

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 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 $\geq$ 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. OPT with verteporfin is covered for the above indication and will remain noncovered for all other indications related to AMD (see CIM § CIM § 35-100). OPT with Verteporfin for use in non-AMD conditions is eligible for coverage through individual contractor discretion.

45-31 INTRAVENOUS IMMUNE GLOBULIN FOR THE TREATMENT OF AUTOIMMUNE MUCOCUTANEOUS BLISTERING DISEASES

Intravenous immune globulin (IVIg) is a blood product prepared from the pooled plasma of donors. It has been used to treat a variety of autoimmune diseases, including mucocutaneous blistering diseases. It has fewer side effects than steroids or immunosuppressive agents.

Effective October 1, 2002, IVIg is covered for the treatment of biopsy-proven (1) Pemphigus Vulgaris, (2) Pemphigus Foliaceus, (3) Bullous Pemphigoid, (4) Mucous Membrane Pemphigoid (a.k.a., Cicatricial Pemphigoid), and (5) Epidermolysis Bullosa Acquisita for the following patient subpopulations:

1. Patients who have failed conventional therapy. Contractors have the discretion to define what constitutes failure of conventional therapy;

2. Patients in whom conventional therapy is otherwise contraindicated. Contractors have the discretion to define what constitutes contraindications to conventional therapy; or

3. Patients with rapidly progressive disease in whom a clinical response could not be affected quickly enough using conventional agents. In such situations IVIg therapy would be given along with conventional treatment(s) and the IVIg would be used only until the conventional therapy could take effect.

In addition, IVIg for the treatment of autoimmune mucocutaneous blistering diseases must be used only for short-term therapy and not as a maintenance therapy. Contractors have the discretion to decide what constitutes short-term therapy.

45-32 LEVOCARNITINE FOR USE IN THE TREATMENT OF CARNITINE DEFICIENCY IN ESRD PATIENTS

Carnitine is a naturally occurring substance that functions in the transport of long-chain fatty acids for energy production by the body. Deficiency can occur due to a congenital defect in synthesis or utilization, or from dialysis. The causes of carnitine deficiency in hemodialysis patients include dialytic loss, reduced renal synthesis and reduced dietary intake.

Intravenous levocarnitine, for one of the following indications, will only be covered for those ESRD patients who have been on dialysis for a minimum of three months.

Patients must have documented carnitine deficiency, defined as a plasma free carnitine level<40 micromol/L (determined by a professionally accepted method as recognized in current literature), along with signs and symptoms of:

1. Erythropoietin–resistant anemia (persistent hematocrit <30% with treatment) that has not responded to standard erythropoietin dosage (that which is considered clinically appropriate to treat the particular patient) with iron replacement, and for which other causes have been investigated and adequately treated, or

2. Hypotension on hemodialysis that interferes with delivery of the intended dialysis despite application of usual measures deemed appropriate (e.g., fluid management). Such episodes of hypotension must have occurred during at least 2 dialysis treatments in a 30-day period.

Continued use of levocarnitine will not be covered if improvement has not been demonstrated within 6 months of initiation of treatment. All other indications for levocarnitine are non-covered in the ESRD population.

For a patient currently receiving intravenous levocarnitine, Medicare will cover continued treatment if:

1. Levocarnitine has been administered to treat erythropoietin-resistent anemia (persistent hematocrit <30 percent with treatment) that has not responded to standard erythropoietin dosage (that which is considered clinically appropriate to treat the particular patient) with iron replacement, and for which other causes have been investigated and adequately treated, or hypotension on hemodialysis that interferes with delivery of the intended dialysis despite application of usual measures deemed appropriate (e.g., fluid management) and such episodes of hypotension occur during at least 2 dialysis treatments in a 30-day period; and

2. The patient's medical record documents a pre-dialysis plasma free carnitine level <40 micromol/L prior to the initiation of treatment; or

3. The treating physician certifies (documents in the medical record) that in his/her judgment, if treatment with levocarnitine is discontinued, the patient's pre-dialysis carnitine level would fall below 40 micromol/L and the patient would have recurrent erythropoietin-resistant-anemia or intradialytic hypotension.