Medicare Coverage Issues Manual

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

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CHANGE REQUEST 1322

HEADER SECTION NUMBERS	PAGES TO INSERT	PAGES TO DELETE
Table of Contents	2 pp.	2 pp.
45-29	1 p.	1 p.

NEW/REVISED MATERIAL--*EFFECTIVE DATE: 12/01/00*
IMPLEMENTATION DATE:12/01/00

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, fiscal intermediaries, Peer Review Organizations, Health Maintenance Organizations, Competitive Medical Plans, Health Care Prepayment Plans, and Medicare+Choice Organizations (§1852 (a)(1)(A)). In addition, an administrative law judge may not disregard, set aside, or otherwise review a national coverage decision issued under §1862(a)(1) of the Act and 42 CFR §405.860.

Section 45-29, Intravenous Iron Therapy, is revised to add *sodium ferric gluconate complex in 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 this drug.

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.

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 (effective for services performed on or after12/01/00)

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 erythropoeitin therapy.