

## National Coverage Determination

### Subject

*Intravenous Iron Therapy*

### NCD Number

INJ-035

### Effective Date

\*N/A

### Indications and Limitations of Coverage

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

### Source

CMS Pub.100-3 §110.10; CIM §45-29

### Notes

In accordance with CMS regulations/instructions, as a result of legislative changes the coding, billing instruction and other information have been removed from this NCD document and placed in a companion article. See [Intravenous Iron Therapy INJ-035: Billing and Coding Guidelines](#)

*NCDs are binding on all carriers, fiscal intermediaries, quality improvement 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 Medicare Advantage Organizations. In addition, an administrative law judge may not review an NCD. (See §1869(f)(1)(A)(i) of the Social Security Act.)*

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An asterisk (\*) indicates a revision to that section of the NCD.

*Carriers may cover other uses of this drug at their discretion.*

**Dates**

**Date Published**

\*07/01/2006 (article); 01/01/2006; 10/01/2005 (article); 12/01/2004; 04/01/2003; Article 12/01/2001; 08/01/2001

**Effective Date/Number/Explanation**

\*N/A Six (Comp. Art. Rev); Multiple Five (Add ICD-9s); 10/01/2005 Four (06 ICD-9 UD); 12/01/2004 Three (new format); 01/01/2003 Two (03 HCPCS); 01/01/2002 One (02 HCPCS)