

## Iron Therapy, Intravenous

Date of Origin: 04/2008

Last Review Date: 04/22/2020

Effective Date: 05/01/2020

Dates Reviewed: 04/2009, 04/2012, 02/2013, 01/2014, 01/2015, 05/2016, 04/2020

Developed By: Medical Necessity Criteria Committee

### I. Description

Iron is an essential nutrient that is needed by every cell in the body. It plays an important role in the transport and storage of oxygen and in cell growth and proliferation. Iron also has an important role in the production of hemoglobin and myoglobin.

Iron deficiency is the depletion of iron stores to the point that red blood cell production is impaired. Iron deficiency is the most common deficiency disease worldwide. Causes of iron deficiency may include inadequate iron intake through diet, blood loss through surgery or hemorrhage, inflammatory bowel disease, or dialysis. Many people can be treated with oral iron preparations but in some cases oral iron may not be adequate to treat the iron deficiency. In these situations, intravenous iron therapy is the preferred treatment.

### II. Criteria: CWQI HCS-0047

- A. Moda Health will cover intravenous iron therapy for iron deficiency anemia (as defined as a hemoglobin (Hgb) level < 13 g/dL in men and < 12 g/dL in women; serum ferritin levels in adults > 5 years of age < 15 ng/ml, children < 5 years of age level <12) to plan limitations when administered at a facility or clinic with continuous monitoring when **one** or more of the following criteria are met:
- Patient requires iron supplementation and is unable to tolerate oral forms of iron; **or**
  - Patient requires iron supplementation and oral iron supplementation is ineffective; **or**
  - Iron depletion is at a rate too rapid for oral iron intake to compensate for the loss (i.e. significant blood loss); **or**
  - Patient requires iron supplementation but has a gastrointestinal tract disorder, such as ulcerative colitis, in which symptoms may be aggravated by oral iron therapy; **or**
  - Patient has chemotherapy induced anemia; **or**
  - Patient has renal disease and is undergoing hemodialysis or peritoneal dialysis and receiving epoietin therapy; **or**
  - Patient is donating large amounts of blood for auto transfusion program.
- B. If the patient meets any of the above criteria, Moda Health will cover intravenous iron therapy for 6 months.
- C. Moda Health considers intravenous iron therapy investigational for all other indications

### III. Information Submitted with the Prior Authorization Request:

- Chart notes from treating physician documenting iron deficiency anemia.
- Documentation of previous treatment for anemia

IV. CPT or HCPC codes covered:

Codes	Description
J1750	Injection, iron dextran, 50mg
J1756	Injection, iron sucrose, 1mg
J2916	Injections, sodium ferric gluconate complex in sucrose injection, 12.5mg
J1439	Injection, ferric carboxymaltose, 1 mg
J1443	Injection, ferric pyrophosphate citrate solution, 0.1 mg of iron
Q0138	Injection, ferumoxytol, for treatment of iron deficiency anemia, 1 mg (non-ESRD use)

V. Annual Review History

Review Date	Revisions	Effective Date
02/2013	Annual Review: Added table with review date, revisions, and effective date	03/1/2013
01/2014	Annual Review: Added #8 that IV Iron is administered in a medical setting with continuous monitoring.	01/22/2014
01/2015	Annual Review: Deleted #8 and included in the criteria description in I.	01/28/2015
05/2016	Annual Review: Added definition for iron deficiency anemia, added additional HCPC codes	05/26/2016
05/2017	Annual Review: Updated to new template, added new code J1443	05/25/2017
04/2020	Annual Review: No changes	05/01/2020

VI. References

1. Guidelines for Anemia Management. Accessed on February 26, 2013, available at URL address: [www.venofer.com](http://www.venofer.com)
2. Auerbach M, Ballard H, Trout R, et al. Intravenous iron optimizes the response to recombinant human erythropoietin in cancer patients with chemotherapy-related anemia: a multicenter, open-label, randomized trial. J Clin Oncol. 2004; 22:1301-1307.
3. Singh H, Reed J, Noble S, et al. Effects of intravenous iron sucrose in peritoneal dialysis patients who receive erythropoiesis-stimulating agents for anemia: a randomized, controlled trial. Clin J Am Soc Nephrol. 2006 Jan; 1:475-482.

4. Richardson D, Bartlett C, Jolly H, Will E. intravenous iron for CAPD populations: proactive or reactive strategies? *Nephrol Dial Transplan.* 2001; 16:115-119.
5. Van Wyck D, Danielson B, Aronoff G. Making sense: a scientific approach to intravenous iron therapy. *J Am Soc Nephrol.* 2004. 15: S91-S92.
6. National Kidney Foundation. NKF KDOQI Clinical Practice Guideline and Clinical Practice Recommendations for Anemia in Chronic Kidney Disease: 2007 Update of Hemoglobin Target. Accessed on April 16, 2012. Available at URL address: [http://www.kidney.org/professionals/KDOQI/guidelines\\_anemia/cpr12.htm](http://www.kidney.org/professionals/KDOQI/guidelines_anemia/cpr12.htm)
7. Henry DH. The role of intravenous iron in cancer-related anemia. *Oncology (Williston Park).* 2006 Jul;20(8Suppl 6):21-4.
8. Pedrazzoli P, Farris A, Del Prete S, et al. Randomized trial of intravenous iron supplementation in patients with chemotherapy-related anemia without iron deficiency treated with darbepoetin alpha. *J Clin Oncol.* 2008 Apr 1;26(10):1619-25.
9. American College of Obstetricians and Gynecologists (ACOG). Anemia in pregnancy. ACOG Practice Bulletin No. 95. Washington, DC: ACOG; July 2005.
10. National Coverage Determination (NCD) for Intravenous Iron Therapy (110.10), accessed January 17, 2014 at: <http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=156&ncdver=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=Ore gon&Keyword=Intravenous+iron&KeywordLookUp=Title&KeywordSearchType=And&CptHcpcsCode=J1750&bc=gAAAAABAAAA&>
11. WHO: Haemoglobin concentrations for the diagnosis of anaemia and assessment of severity; Vitamin and Mineral Nutrition Information System. Geneva, World Health Organization, 2011 (WHO/NMH/NHD/MNM/11.1); <http://www.who.int/vmnis/indicators/haemoglobin.pdf>
12. U.S. National Library of Medicine; U.S. Department of Health and Human Services National Institutes of Health; Medline Plus; Ferritin Blood Test; Last updated: 02 March 2016
13. 1998-2016 Mayo Foundation for Medical Education and Research; PRC-20014449; Ferritin Test
14. Healthline; Rachel Nall, Steven Kim, M.D.; Ferritin Level Blood Test; October 1, 2015
15. WHO Serum ferritin concentrations for the assessment of iron status and iron deficiency in populations. Vitamin and Mineral Nutrition Information System. Geneva, World Health Organization, 2011 (WHO/NMH/NHD/MNM/11.2); <http://www.who.int/vmnis/indicators/serumferritin.pdf>
16. Physician Advisors

## Appendix 1 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

Jurisdiction(s): 5, 8	NCD/LCD Document (s):
National Coverage Determination (NCD) 110.10 Intravenous Iron Therapy	
<a href="https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=156&amp;ncdver=1&amp;DocID=110.10&amp;kq=true&amp;bc=gAAAABAAAAAAAA%3d%3d&amp;">https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=156&amp;ncdver=1&amp;DocID=110.10&amp;kq=true&amp;bc=gAAAABAAAAAAAA%3d%3d&amp;</a>	

NCD/LCD Document (s):

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC