PrimeWest HEALTH™
Your greater Minnesota health plan

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PrimeWest Health Intravenous Iron Therapy
Part B Step Therapy Criteria

Effective 1/01/2022
Last updated 02/2023

I. Initial Criteria

Due to a lack of clear superiority of clinical outcomes, safety, or patient tolerability, Part B step therapy is required for: Feraheme (ferumoxytol) Q0138 and Q0139, Injectafer (ferric carboxymaltose) C9441, Q9970, J1439, Monoferric (ferric derisomaltose) J1437, Triferic (ferric pyrophosphate citrate) Q9976, J1443, Triferic Avnu (ferric pyrophosphate citrate injection for IV use) J1445.

Based on safety and efficacy, authorization is required for any IV iron preparations not listed in #1 below.

1. Trial of at least 3 weeks of therapy, and failure is required of at least <u>one</u> of the following products:
   a. Iron sucrose J1756
   b. Iron dextran J1751, J1752
   c. Sodium Ferric Gluconate Complex (Ferrlicit) J2916; OR
2. History of contraindication, intolerance or adverse event(s) to at least one of the preferred intravenous iron therapies; OR
3. Continuation of prior therapy within the past 365 days; AND
4. Iron deficiency as evidence by: Patient has iron-deficiency anemia with a Hemoglobin (Hb) <12 g/dL; **AND any laboratory value reflective of low iron state such as iron level, ferritin, etc.**

<u>Renewal Review:</u> Refer to initial criteria.

II. References

1. Injectafer [package insert]. Shirley, NY; American Regent, Inc. January 2018. Accessed May 2018.
2. Onken JE, Bregman DB, Harrington RA, et al. A multicenter, randomized, active-controlled study to investigate the efficacy and safety of intravenous ferric carboxymaltose in patients with iron deficiency anemia. Transfusion. 2014 Feb;54(2):306-15.
3. Onken JE, Bregman DB, Harrington RA, et al. Ferric carboxymaltose in patients with iron- deficiency anemia and impaired renal function: the REPAIR-IDA trial. Nephrol Dial Transplant. 2014 Apr;29(4):833-42.
4. KDOQI; National Kidney Foundation. Clinical practice guidelines and clinical practice recommendations for anemia in chronic kidney disease in adults. Am J Kidney Dis.2006 May;47(5 Suppl 3):S16-85.
5. Kidney Disease: Improving Global Outcomes (KDIGO) Anemia Work Group. KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease. Kidney inter., Suppl. 2012; 2: 279–335.
6. Ratcliffe LE, Thomas W, Glen J, et al. Diagnosis and Management of Iron Deficiency in CKD: A Summary of the NICE Guideline Recommendations and Their Rationale. Am J Kidney Dis. 2016 Apr;67(4):548-58.
7. Referenced with permission from the NCCN Drugs and Biologics Compendium (NCCN Compendium®) ferric carboxymaltose. National Comprehensive Cancer Network, 2018. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®,

and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc." To view themost recent and complete version of the Compendium, go online to NCCN.org. Accessed May 2018.

8. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Cancer- and Chemotherapy-Induced Anemia Version 2.2018. National Comprehensive Cancer Network, 2018. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc." To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed May 2018.
9. Wish JB. Assessing iron status: beyond serum ferritin and transferrin saturation. Clin J Am Soc Nephrol. 2006 Sep;1 Suppl 1:S4-8.
10. Koch TA, Myers J, Goodnough LT. Intravenous Iron Therapy in Patients with Iron Deficiency Anemia: Dosing Considerations. Anemia. 2015;2015:763576.NCD - Intravenous Iron Therapy (110.10) – CMS Updated on 01/20/2021. Accessed 02/22/2023
11. Triferic Avnu [package insert]. Wixom, MI; Roxwell Medical, Inc. March, 2020. Accessed March 2022.
12. CMS Memorandum titled Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage, dated August 7, 2018; see: https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/MA_Step_Therapy_HPMS_Memo_8_7_2018.pdf.

III. CMS information

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.