Blue Cross Blue Shield Blue Care Network of Michigan

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Medical benefit drug policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

Effective Date: 08/08/2024

Intravenous Iron Replacement

Feraheme® (ferumoxytol)
Generic Ferrlect® (sodium ferric gluconate complex)
INFeD (iron dextran)
Injectafer® (ferric carboxymaltose)
Monoferric® (ferric derisomaltose)
Triferic®/Triferic AVNU® (ferric pyrophosphate citrate)
Venofer® (iron sucrose)

HCPCS: Multiple

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

Note: This policy pertains to Medicare Part B only

A. Coverage of the requested drug is provided when all the following are met:
   a. FDA approved indication
   b. Trial and failure, contraindication, OR intolerance to oral iron and the preferred drugs as listed in BCBSM/BCN's utilization management medical drug list

B. Quantity Limitations, Authorization Period and Renewal Criteria
   a. Quantity Limits: Align with FDA recommended dosing
   b. Authorization Period: One year at a time
   c. Renewal Criteria: Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit

***Note: Coverage and approval duration may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at http://www.cms.hhs.gov/. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Background Information:

- The most common causes of iron deficiency anemia are decreased dietary intake, reduced absorption, and blood loss. In resource-rich countries such as the United States, the major cause of iron deficiency is blood loss, either overt or occult. Overt bleeding is usually caused by trauma, hematemesis or melena, hemoptysis, menorrhagia, pregnancy and delivery, or hematuria. Occult bleeding is usually caused by gastrointestinal conditions, such as, gastritis, malignancy, or telangiectasia or hemolysis with urinary losses. The most common symptoms of anemia are fatigue, weakness, headache, irritability, exercise intolerance, shortness of breath on exertion, vertigo, and angina. Diagnosis of iron deficiency anemia is made by low hemoglobin and hematocrit levels and serum ferritin level. Serum ferritin is the key indicator of iron stores in otherwise healthy adults.

- The treatment for iron deficiency anemia is iron replacement, usually with oral over-the-counter (OTC) iron preparations or via intravenous iron. In the presence of functioning erythropoiesis, iron supplementation is adequate to replenish iron stores and restore blood loss. However, due to the gastrointestinal adverse effects of oral iron as well as absorption issues, intravenous iron may be preferable.

- There are currently multiple intravenous iron therapies on the market. Neither the 2012 Kidney Disease: Improving Global Outcomes (KDIGO clinical practice guideline for anemia in chronic kidney disease or the 2024 National Comprehensive Cancer Network hematopoietic growth factors treatment guidelines recommend one intravenous product over another. All have similar efficacy and there is no head to head data showing superiority of one product over the other. Choice of therapy should be based on patient characteristics, side effect profiles, cost, and availability.

References:

1. Feraheme [prescribing information]. Waltham, MA: AMAG Pharmaceuticals, Inc.; June 2022.
2. Ferrlecit [prescribing information]. Bridgewater, NJ: Sanofi-Aventis US, LLC; March 2022.
3. INFeD [prescribing information]. Madison, NJ: Allergan USA, Inc.; September 2021.
4. Injectafer [prescribing information]. Shirley, NY: American Regent, Inc.; May 2023.
5. Triferic AVNU [prescribing information]. Wixom, MI: Rockwell Medical, Inc.; March 2020.
6. Venofer [prescribing information]. Shirley, NY: American Regent, Inc.; June 2022.
7. Monoferric [prescribing information]. Morristown, NJ: Pharmacosmos Therapeutics Inc.; February 2022.
8. National Comprehensive Cancer Network. Hematopoietic growth factors (Version 3.2024). 2024 January 30. Available at: https://www.nccn.org/professionals/physician_gls/pdf/growthfactors.pdf. Accessed on May 30, 2024.
9. Adkinson NF, Strauss WE, Macdougall IC, et al. Comparative safety of intravenous ferumoxytol versus ferric carboxymaltose in iron deficiency anemia: a randomized trial. Am J Hematol. 2018; 93: 683.
10. Hetzel D, Strauss W, Bernard K, et al. A phase III, randomized, open-label trial of ferumoxytol compared with iron sucrose for the treatment of iron deficiency anemia in patients with a history of unsatisfactory oral iron therapy. Am J Hematol. 2014; 89: 646.
11. Macdougall IC, Strauss WE, McLaughlin J, et al. A randomized comparison of ferumoxytol and iron sucrose for treating iron deficiency anemia in patients with CKD. Clin J Am Soc Nephrol. 2014; 9: 705.
12. Eknoyan G, Lameire N, Kasiske BL, et al. KDIGO clinical practice guideline for anemia in chronic kidney disease. 2012 August 2. J Intern Society of Nephrol. 2 (4): 282- 335.

Policy History		
#	Date	Change Description
1.4	Effective Date: 08/08/2024	Annual review of criteria was performed, no changes were made
1.3	Effective Date: 08/10/2023	Annual review of criteria was performed, no changes were made
1.2	Effective Date: 08/08/2022	UM medical management system update for Injectafor and Monoferric for BCNA and MAPPO
1.1	Effective Date: 08/04/2022	Updated criteria to require the use of more than one preferred product
1.0	Effective Date: 06/10/2021	New policy for Medicare Part B only

** The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or http://dailymed.nlm.nih.gov/dailymed/index.cfm.*