Pharmacy Management Drug Policy

SUBJECT: Intravenous Iron Replacement Products
POLICY NUMBER: PHARMACY-116
EFFECTIVE DATE: 02/2024
LAST REVIEW DATE: 07/16/2026

If the member's subscriber contract excludes coverage for a specific service or prescription drug, it is not covered under that contract. In such cases, medical or drug policy criteria are not applied. This drug policy applies to the following line/s of business:

Policy Application

Category:	☒ Commercial Group (e.g., EPO, HMO, POS, PPO)	☒ Medicare Advantage
	☒ On Exchange Qualified Health Plans (QHP)	☐ Medicare Part D
	☒ Off Exchange Direct Pay	☒ Essential Plan (EP)
	☒ Medicaid & Health and Recovery Plans (MMC/HARP)	☒ Child Health Plus (CHP)
	☐ Federal Employee Program (FEP)	☐ Ancillary Services
	☒ Dual Eligible Special Needs Plan (D-SNP)	

DESCRIPTION:

Iron deficiency (ID) affects more than 2 billion people worldwide and is estimated to affect approximately 8 to 9 million people in the United States.[1] It is the most common nutritional disorder worldwide, accounting for approximately one-half of all anemia cases.[2] Iron deficiency anemia (IDA) occurs when iron deficiency becomes severe enough to reduce erythropoiesis. The causes of iron deficiency anemia are numerous, including gastrointestinal bleeding or other blood loss, chronic kidney disease, celiac disease, multiple blood donations, and cancer or chemotherapy-related etiologies. A diagnosis of iron deficiency anemia requires laboratory-confirmed evidence of anemia, defined as a hemoglobin level two standard deviations below normal for age and sex, as well as evidence of low iron stores.[2] Serum ferritin reflects iron stores and is the most accurate test to diagnose iron deficiency anemia (ferritin < 30 ng/mL).[2] However, as ferritin is an acute phase reactant, it may be elevated in patients with malignancy, chronic inflammation, or infection. Therefore, a normal ferritin concentration alone does not necessarily exclude iron deficiency.[13] Additional values consistent with iron deficiency include a low serum iron level, low transferrin saturation, and a high total iron-bonding capacity.[2] Identifying the underlying etiology and administering the appropriate therapy, in addition to iron replacement therapy, are keys to the evaluation and management of this condition.[2]

Oral iron preparations (e.g., ferrous sulfate, ferrous gluconate, ferrous fumarate) are usually first line treatment for iron replacement. Most patients are treated with oral iron preparations because they are effective, readily available, inexpensive, and safe.[6] Parenteral iron therapy is recommended in patients who cannot tolerate or absorb oral preparations, such as those who have undergone bariatric or other GI surgery. The most common indications for intravenous therapy are gastrointestinal side effects, worsening symptoms of inflammatory bowel disease, unresolved bleeding, and insufficient absorption in patients with celiac disease.[2] Intravenous iron is essential in the management of anemia in patients with chronic kidney disease who are receiving dialysis and treatment with erythropoiesis-stimulating agents.[3] The addition of iron supplementation may eliminate or delay the need for these agents in some patients with chronic kidney disease who are not receiving dialysis.[4,5]

The Kidney Disease Improving Global Outcomes practice guidelines for anemia in chronic kidney disease (KDIGO; 2012) include recommendations for the use of IV iron supplements in patients with chronic kidney disease (CKD).[11] For adult CKD patients with anemia not on iron or erythroid stimulating agent (ESA) therapy, a trial of IV iron is recommended if an increase in hemoglobin (Hb) concentration without starting ESA treatment is desired and transferrin saturation (TSAT) is ≤ 30% and

ferritin is ≤ 500 ng/mL. For adult CKD patients on ESA therapy who are not receiving iron supplementation, a trial of IV iron is recommended if an increase in Hb concentration or a decrease in ESA dose is desired and TSAT is ≤ 30% and ferritin is ≤500 ng/mL. For adult non-dialysis CKD patients, a one to three month trial of oral iron may be tried initially but usually cannot maintain adequate iron stores. For all pediatric CKD patients with anemia not on iron or ESA therapy, oral iron (or IV iron for patients receiving hemodialysis) is recommended when TSAT is ≤ 20% and ferritin is ≤ 100 ng/mL. For all pediatric CKD patients on ESA therapy who are not receiving iron supplementation, oral iron (or IV iron for patients receiving hemodialysis) is recommended to maintain TSAT > 20% and ferritin > 100 ng/mL.

The National Comprehensive Cancer Network Drugs and Biologics Compendium (NCCN,2023) recommend consideration for the use of IV iron supplementation for management of cancer- and chemotherapy-induced anemia. IV iron therapy is considered an option for patients with absolute iron deficiency (ferritin < 30ng/mL and TSAT < 20%), functional iron deficiency in patients receiving ESAs (ferritin 30-500 ng/mL and TSAT <50%), and possible functional iron deficiency (ferritin > 500-800 ng/mL and TSAT < 50%).[15]

According to the 2017 focused update of the 2013 American College of Cardiology Foundation/American Heart Association guideline for the management of heart failure, anemia is independently associated with heart failure disease severity, and iron deficiency appears to be uniquely associated with reduced exercise capacity.[16] In patients with New York Heart Association class II or III heart failure and iron deficiency (ferritin < 100 ng/mL or 100 to 300 ng/mL if TSAT < 20%), IV iron replacement may be reasonable to improve function status and quality of life. Benefits noted with IV iron therapy included improvement in in the six-minute walk test, fatigue, and quality of life score over time.[17]

Multiple parenteral iron replacement products are currently available, including ferric carboxymaltose, ferric gluconate, ferumoxytol, iron sucrose, ferric derisomaltose, and low molecular weight iron dextran. After injection, the different preparations all share a similar fate. The iron complexes mix with plasma and are phagocytosed within the reticuloendothelial system, wherein the carbohydrate shell is degraded, and iron is stored as ferritin or transported out of the cell, bound to transferrin, which delivers iron to its destiny.[8,18] All of these formulations are equally effective in treating iron deficiency and have a similar safety profile.[6,9,10] Hypersensitivity reactions have been reported with intravenous iron. Practical recommendations for minimizing risk include a slow infusion rate, careful patient observation, and administration by trained healthcare personnel in an environment with access to resuscitation facilities.[1,7] Factors which may influence which product is selected include patient diagnosis, prior treatments, length of infusion, and the number of infusions required to complete the full course of treatment.

Feraheme (ferumoxytol injection)
Feraheme is indicated for the treatment of iron deficiency anemia in adult patients who have intolerance to oral iron or have had unsatisfactory response to oral iron, or for patients who have chronic kidney disease. The recommended dose of Feraheme is an initial 510 mg dose followed by a second 510 mg dose 3 to 8 days later. Feraheme is administered as an IV infusion in 50-200 mL 0.9% sodium chloride injection, or 5% dextrose injection, over at least 15 minutes. Due to the risk of clinically significant hypotension, Feraheme should be administered to patients while in a reclined or semi-reclined position.

Ferrlecit (sodium ferric gluconate complex injection)
Ferrlecit is an iron replacement product for the treatment of iron deficiency anemia in adult and pediatric patients aged 6 years and older with chronic kidney disease receiving hemodialysis who are receiving supplemental epoetin therapy. The recommended adult dosage of Ferrlecit is 10 mL (125 mg of elemental iron) diluted in 100 mL of 0.9% sodium chloride administered by IV infusion over one hour per dialysis session or undiluted as a slow intravenous injection (at a rate of up to 12.5 mg/min) per dialysis session. For repletion treatment most patients require a cumulative dose of 1000 mg of elemental iron administered over 8 dialysis sessions. The recommended pediatric dosage of Ferrlecit is 0.12 mL/kg (1.5 mg/kg of elemental iron) diluted in 25 mL 0.9% sodium chloride and administered by IV infusion over 1 hour per dialysis session. The maximum dosage should not exceed 125 mg per dose.

Infed (iron dextran injection)
Infed is an iron replacement product indicated for the treatment of adult and pediatric patients of age 4 months and older with documented iron deficiency who have intolerance to oral iron or an unsatisfactory response to oral iron. Anaphylactic-type reactions have been reported following the parenteral administration of iron dextran injection and a test dose of Infed should be administered to check for hypersensitivity reactions prior to administration of the therapeutic dose. The recommended dosage of Infed is individualized based on a calculation using the patients lean body weight (or actual body weight for those 5 to 15 kg), observed hemoglobin level, and desired hemoglobin. A separate calculation is used for the recommended dosage of iron replacement due to blood loss. Daily doses of Infed should not exceed 2 mL, which may necessitate infusions over multiple days to administer the required therapeutic dose.

Injectafer (ferric carboxymaltose injection)
Injectafer is an iron replacement product indicated for the treatment of iron deficiency anemia in adult and pediatric patients 1 year of age and older who have either intolerance or an unsatisfactory response to oral iron and for adult patients who have non-dialysis dependent chronic kidney disease. Injectafer is also indicated for the treatment of iron deficiency in adult patients with heart failure and New York Heart Association class II/III to improve exercise capacity. The recommended dosage of Injectafer for the treatment of iron deficiency anemia is weight based. For patients weighing 50 kg or more, the recommended dosage is 750 mg administered intravenously in two doses separated by at least 7 days for a cumulative dose of 1,500 mg of iron per course. Alternatively, Injectafer 15 mg/kg body weight up to a maximum of 1,000 mg IV may be administered as a single-dose per course. For patients weighing less than 50 kg, the recommended dosage of Injectafer is 15 mg/kg body weight administered intravenously in two doses separated by at least 7 days per course. The recommended dosage of Injectafer for the treatment of iron deficiency with heart failure is based upon patients' weight and current hemoglobin level. Injectafer should be administered as an undiluted slow intravenous push or by infusion.

Monoferric (ferric derisomaltose injection)
Monoferric is an iron replacement product indicated for the treatment of iron deficiency anemia in adult patients who have intolerance to oral iron or have had unsatisfactory response to oral iron or who have non-hemodialysis dependent chronic kidney disease. The recommended dosage of Monoferric for patients weighing 50 kg or more is 1,000 mg by IV infusion over at least 20 minutes as a single dose. For patients weighing less than 50 kg, the recommended Monoferric dosage is 20 mg/kg actual body weight by IV infusion over at least 20 minutes as a single dose.

Venofer (iron sucrose injection)
Venofer is an iron replacement product indicated for the treatment of iron deficiency anemia in patients with chronic kidney disease. The dose and frequency of administration varies for patients who are

dialysis and non-dialysis dependent. For adult patients with hemodialysis dependent-chronic kidney disease (HDD-CKD), the recommended Venofer dose is 100 mg undiluted as a slow IV injection over 2 to 5 minutes, or as an infusion of 100 mg diluted in a maximum of 100 mL 0.9% NaCl over a period of at least 15 minutes, per consecutive hemodialysis session. The usual treatment course of Venofer is 1000mg. For adult patients with non-dialysis dependent-chronic kidney disease (NDD-CKD), the Venofer dose is 200 mg undiluted as a slow IV injection over 2 to 5 minutes, or as an infusion of 200 mg in a maximum of 100 mL of 0.9 NaCl over a period of 15 minutes. Venofer should be administered on 5 different occasions over a 14-day period. For adult patients with peritoneal dialysis dependent-chronic kidney disease (PDD-CKD), the dosage of Venofer should be administered in 3 divided doses, given by slow IV infusion within a 28-day period. Patients should receive 2 infusions of 300 mg over 1.5 hours 14 days apart followed by one 400 mg infusion over 2.5 hours 14 days later. Venofer is indicated for iron maintenance treatment in pediatric patients 2 years of age and older with HDD-CKD. Venofer should be administered at a dose of 0.5 mg/kg, not to exceed 100 mg per dose, every 2 weeks for 12 weeks given undiluted by slow IV injection over 5 minutes or diluted in 0.9% NaCl at a concentration of 1 to 2 mg/mL and administered over 5 to 60 minutes. For pediatric patients 2 years of age and older with NDD-CKD or PDD-CKD who are on erythropoietin therapy, Venofer is administer for iron maintenance therapy at a dose of 0.5mg/kg, not to exceed 100 mg per dose, every 4 weeks for 12 weeks. Venofer should be administer undiluted as a slow IV injection over 5 minutes or diluted in 0.9% NaCl at a concentration of 1 to 2 mg/mL and administered over 5 to 60 minutes.

POLICY:

Injectafer and generic ferric carboxymaltose

****Prior Authorization applies to new starts and existing users for the Commercial, Essential, Exchange, Child Health Plus, and Medicaid/HARP lines of business. Prior Authorization applies to new starts only for the Medicare Advantage and D-SNP lines of business.****

1. Must meet **ONE** of the following **(a or b)**:
    a. Must have a diagnosis of Iron Deficiency (ID) in adult patients with New York Heart Association functional class II or III heart failure with left ventricular ejection fraction (LVEF) < 45% defined as:
        i. Hemoglobin < 15 g/dL **AND**
        ii. Serum ferritin
            1. < 100 ng/mL **OR**
            2. 100 to 300 ng/mL and transferrin saturation (TSAT) ≤ 30%
    b. Must have a diagnosis of Iron Deficiency Anemia (IDA)
        i. Without a diagnosis of chronic kidney disease (CKD) in patients 1 year of age or older
            1. Must have an unsatisfactory response, intolerance, or contraindication to oral iron administration
            2. IDA without CKD is defined as:
                a. For pediatric patients 1 year to < 5 years of age:
                    i. Serum ferritin < 15 µg/L **AND**
                    ii. Hemoglobin < 11 g/dL
                b. For pediatric patients 5 to 12 years of age
                    i. Serum ferritin < 15 µg/L **AND**
                    ii. Hemoglobin < 11.5 g/dL
                c. For adults and pediatric patients > 12 years of age **without** acute or chronic inflammatory conditions:
                    i. Serum ferritin < 30 ng/mL **OR**
                    ii. Transferrin saturation (TSAT) < 20%

d. For adults and pediatric patients > 12 years of age **with** acute or chronic inflammatory conditions:
   i. Serum ferritin < 100 ng/mL **OR**
   ii. If serum ferritin is 100 to 300 ng/mL, must have TSAT < 20%

ii. With a diagnosis of non-dialysis dependent chronic kidney disease (NDD-CKD) in adult patients defined as:
   1. Hemoglobin ≤ 11.5 g/dL **AND**
   2. Serum ferritin
      a. ≤ 100 ng/mL **OR**
      b. ≤ 300 ng/mL and TSAT ≤ 30%

2. All requests for Injectafer or ferric carboxymaltose will require a medical reason why Feraheme (ferumoxytol) cannot be used with the exception of the following:
   a. Patients less than 18 years of age **OR**
   b. Adult patients with New York Heart Association functional class II or III heart failure with left ventricular ejection fraction (LVEF) < 45%
3. Injectafer and ferric carboxymaltose will not be authorized for any non-FDA approved indication
4. Initial approval will be for 6 months
5. Recertifications will be approved for 1 year at a time and will require documentation of positive response to treatment.
6. See the Injectafer Prescribing Information for approved dosage and administration.

Based upon our assessment, the Health Plan considers the following medications medically appropriate and covered without prior authorization.

Drug	How Supplied
Feraheme® (ferumoxytol injection), for intravenous use	Single-Dose vials • 510 mg/17 mL
Ferrlecit® (sodium ferric gluconate complex in sucrose injection for intravenous use	Single-dose vials • 62.5 mg/5 mL
Infed® (iron dextran injection), for intravenous use	Single-dose vials • 100 mg/2 mL
Monoferric® (ferric derisomaltose injection), for intravenous use	Single-dose vials • 100 mg/mL • 500 mg/5 mL • 1,000 mg/10 mL
Venofer® (iron sucrose injection), for intravenous use	Single-dose vials • 50 mg/2.5 mL • 100 mg/5 mL • 200 mg/10 mL

POLICY GUIDELINES:

1. Utilization Management is contract dependent. Refer to specific contract/benefit language for exclusions.
   a. Coverage criteria may be dependent on the contract renewal date.
   b. Coverage of drugs listed in this policy are contract dependent.
   c. Not all contracts/benefits allow coverage of healthcare professional administered drugs as part of their pharmacy benefit.

d. Not all contracts/benefits cover all medical infusible drugs.

2. Unless otherwise indicated within drug specific criteria, the drugs listed in this policy are administered by a healthcare professional and therefore are covered under the medical benefit.
3. This policy does not apply to Medicare Part D and D-SNP pharmacy benefits. The drugs in this policy may apply to all other lines of business including Medicare Advantage.
4. For members with Medicare Advantage, medications with a National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) will be covered pursuant to the criteria outlined by the NCD and/or LCD. NCDs/LCDs for applicable medications can be found on the CMS website at https://www.cms.gov/medicare-coverage-database/search.aspx. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS permits a Medicare Advantage Organization (MAO) to establish its own coverage determinations in accordance with 42 CFR § 422.101(b)(6). Indications that have not been addressed by the applicable medication's LCD/NCD will be covered in accordance with criteria determined by the Health Plan (which may include review per the Health Plan's Off-Label Use of FDA Approved Drugs policy). Step therapy requirements may be imposed in addition to LCD/NCD requirements.
5. Clinical documentation must be submitted for each request (initial and recertification [if applicable]) unless otherwise specified (e.g., provider attestation required). Supporting documentation includes, but is not limited to, progress notes documenting previous treatments and treatment history, diagnostic testing, laboratory test results, genetic testing or biomarker results, imaging and other objective or subjective measures of clinical benefit. For recertification, continued approval requires documentation demonstrating that the requested product is providing ongoing benefit to the patient, evidenced by improvement or stability in the disease state or condition, and that continued use remains medically necessary. Ongoing use of the requested product must continue to align with the current policy's preferred formulary. Recertification reviews may result in the requirement to try more cost-effective treatment alternatives as they become available (i.e., generics, biosimilars, or other guideline supported treatment options). Requested dosing must remain consistent with FDA-approved or off-label/guideline-supported dosing recommendations.
6. All requests will be reviewed to ensure they are being used for an appropriate indication and may be subject to an off-label review in accordance with our Off-Label Use of FDA Approved Drugs Policy (Pharmacy-32).
7. Dose and frequency should be in accordance with the FDA label or recognized compendia (for off-label uses). When services are performed in excess of established parameters, they may be subject to review for medical necessity.
8. All utilization management requirements outlined in this policy are compliant with applicable New York State insurance laws and regulations. Policies will be reviewed and updated as necessary to ensure ongoing compliance with all state and federally mandated coverage requirements.
9. Manufacturers may either discontinue participation in, or may not participate in, the Medicaid Drug Rebate Program (MDRP). Under New York State Medicaid requirements, physician-administered drugs must be produced by manufacturers that participate in the MDRP. Products made by manufacturers that do not participate in the MDRP will not be covered under Medicaid Managed Care/HARP lines of business. Drug coverage will not be available for any product from a non-participating manufacturer. For a complete list of New/Reinstated & Terminated Labelers please visit: https://www.medicaid.gov/medicaid/prescriptiondrugs/medicaid-drug-rebate-program/newreinstated-terminated-labeler-information/index.html
10. The requested site of care may impact approval timeframe and is subject to review.
11. This policy is based on available evidence as of the last review date. Coverage determinations are subject to applicable plan documents, state and federal regulations, and individual patient circumstances. This policy does not constitute medical advice.

12. For commercial contracts, medical necessity determinations align with the Certificate of Coverage issued by the Health Plan, which states that covered services must be clinically appropriate and not primarily for the convenience of the member, the member's family, or the provider.
13. This policy is subject to ongoing revision. Newly marketed drugs and existing drugs with new indications may be subject to prior authorization until formal coverage criteria are established. Inclusion of a drug in this policy does not guarantee its current availability on the market, as some agents may be discontinued, withdrawn, or otherwise unavailable. As product status changes, drugs may be removed from the policy.

CODES:

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

Code Key:
Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).
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HCPCS:

Trade Name	Chemical Name	HCPCS codes
Feraheme	Injection, ferumoxytol	Q0138 – for non-ESRD use Q0139 – for ESRD on dialysis
Ferrlecit	Injection, sodium ferric gluconate	J2916
Infed	Injection, iron dextran	J1750
Injectafer	Injection, ferric carboxymaltose	J1439
Monoferric	Injection, ferric derisomaltose	J1437
Venofer	Injection, iron sucrose	J1756

UPDATES:

Date	Revision
07/16/2026	Revised
06/01/2026	Revised
05/14/2026	Reviewed / P&T Committee Approval
11/19/2025	Revised
07/01/2025	Revised
05/08/2025	Reviewed / P&T Committee Approval
03/06/2025	Revised
12/19/2024	Revised
09/13/2024	Revised
06/20/2024	Revised
05/09/2024	Reviewed / P&T Committee Approval
02/01/2024	Policy Implemented

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19. Feraheme [package insert]. Waltham, MA: Amag Pharmaceuticals, Inc.; Revised June 2022
20. Ferrlecit [package insert]. Bridgewater, NJ: Sanofi-Avantis U.S. LLC; Revised March 2022
21. Infed [package insert]. Madison, NJ: Allergan USA, Inc.; Revised September 2021
22. Injectafer [package insert]. Shirley, NY: American Regent, Inc.; Revised May 2023
23. Monoferric [package insert]. Morristown, NJ: Pharmacosmos Therapeutics Inc.; Revised February 2022
24. Venofer [package insert]. Shorley, NY: American Regent, Inc.; Revised June 2022