WellMed Doctors helping patients for more than 25 years	**Effective Date: 04/05/2023**	**Revision Date(s):** 1/21/20, 02/11/21, 06/16/22, 12/15/22, 02/16/23
Department: PHARMACY	**MMC Review/ Approval Date(s):** 03/27/23	**Total Page(s):** 19

Policy Number: 030.005
Title: Coverage Determination Policy for Intravenous Iron Therapy

- **Ferric Carboxymaltose Injection (Injectafer), Ferumoxytol (Feraheme), Ferric Derisomaltose Injection (Monoferric)**

Regions:	☒ Texas	☐ Florida	☐ Indiana	☐ New Jersey	☒ New Mexico

Impacted Areas:

☒ Network Management/Provider Services	☒ Utilization Management
☐ Member services	☐ Case management
☐ Quality Management	☐ Disease management
☐ Credentialing	☒ Claims
☐ IT	☐ Human resources
☐ Administration	☐ Finance
☐ Compliance/delegation	☒ Pharmacy
	☐ ALL

Available LCD/NCD/LCA: National Coverage Determination (NCD) for Intravenous IRON Therapy (110.10). Available at 110.10 (Applicable to end stage renal disease (ESRD) patients undergoing hemodialysis)

Disclaimer:
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Coverage Policy Number: 030.005

Line of Business: Medicare Part B

Policy Type: Prior Authorization

Coverage Determination:

Step Therapy Criteria

This policy supplements the Medicare guidelines such as NCDs, LCDs, and other Medicare manuals for the purposes of determining coverage under the Part B medical benefits. This Step Therapy Policy is implemented to enforce a step therapy requirement for new starts only. This policy is not applicable to members continuing therapy within the past 365 days. Coverage is granted if Medicare Coverage requirements PLUS these step criteria are met.

Non-preferred drug(s): Injectafer, Monoferric

Preferred drug(s): Venofer, Infed, Ferrlecit, Feraheme

Non-preferred Product Criteria

Coverage of Monoferric or Injectafer is medically necessary when **ONE** of the following criteria are met:

A. Submission of laboratory values demonstrating treatment failure after at least 3 weeks of therapy, to at least two of the preferred **intravenous iron therapies** (*lab values should be obtained 1-3 weeks following the last dose of IV iron in a treatment course*)

B. History of intolerance, contraindication or severe adverse event to ALL of the preferred drugs

C. Continuation of prior therapy within the past 365 days

Initial/New Requests

WellMed will cover initiation of Injectafer, Monoferric and Feraheme as medically necessary when the following criteria are met:

- Patient has a diagnosis of iron deficient anemia supported by recent documentation

(*See diagnostic considerations in Clinical Evidence/Professional Guidelines for reference*)

AND EITHER

- A documented intolerance or contraindication to oral iron or a documented unsatisfactory response to oral iron (e.g. late stage pregnancy, impaired absorption due to gastric surgery or inflammatory bowel disease)

OR

- A diagnosis of non-dialysis dependent chronic kidney disease

AND

- Dosing regimen is consistent with FDA-approved labeling. (Refer to dosing table)
- Total Feraheme and Injectafer dose does not exceed 2.04g and 1500mg per treatment course respectively
- Initial authorization does not exceed 3 months

Renewal/Continuation of Therapy Requests

WellMed will cover renewal of Injectafer, Monoferric and Feraheme as medically necessary when **ALL** of the following criteria are met:

A. Documentation of positive clinical response to Injectafer, Monoferric and Feraheme (such as improvement in Hgb and/or ferritin level and/or TSAT and/or TIBC, improvement in anemia symptoms)

B. Documentation of reoccurrence of iron deficiency anemia after previous treatment course from recent lab results (within past 4 weeks)

C. Lack of serious adverse effects from Injectafer, Monoferric and Feraheme (e.g. anaphylactic-type or hypersensitivity reactions)

D. Dosing regimen and dose titration is consistent with FDA-approved labeling. (Refer to dosing table)

Note: *WellMed will **NOT** cover Injectafer, Monoferric and Feraheme for any other cause of anemia in the absence of a diagnosis of IDA as Injectafer, Monoferric and Feraheme have not been studied or proven safe and effective for these indications.*

FDA Approved Dose and Indication

Description	FDA Approved Dosing
Ferric Carboxymaltose (Injectafer)	**Iron deficiency anemia, With intolerance or inadequate response to oral iron, or in non-dialysis dependent chronic kidney disease** • Weight 50 kg or greater, 750 mg elemental iron IV followed by 750 mg IV 7 days later; total cumulative dose not to exceed 1500 mg elemental iron • Weight less than 50 kg, 15 mg/kg elemental iron IV followed by 15 mg/kg IV 7 days later; total cumulative dose not to exceed 1500 mg elemental iron
Ferumoxytol (Feraheme)	**Chronic kidney disease - Iron deficiency anemia** • 510 mg elemental iron IV once, followed by a second 510 mg IV dose 3 to 8 days later; may repeat for persistent or recurrent iron deficiency anemia (FDA dosage) • 1020 mg elemental iron diluted in 100 mL NS IV over 15 minutes (off-label dosage) **Iron deficiency anemia, Intolerant or unsatisfactory response to oral iron** • 510 mg elemental iron IV once, followed by a second 510 mg IV dose 3 to 8 days later; may repeat dose for persistent or recurrent iron deficiency anemia
Ferric Derisomaltose (Monoferric)	**Iron deficiency anemia, With intolerance or inadequate response to oral iron, or in non-dialysis dependent chronic kidney disease** • Weight 50 kg or greater, 1000 mg elemental iron IV as a single dose; may repeat dose for persistent or recurrent iron deficiency anemia • Weight less than 50 kg, 20mg/kg elemental iron IV as a single dose; may repeat dose for persistent or recurrent iron deficiency anemia

FDA Approved Indications	FDA Approved Products
• Iron deficiency anemia with intolerance or inadequate response to oral iron • Iron deficiency anemia in non-dialysis dependent chronic kidney disease	• Ferric Carboxymaltose (Injectafer) • Ferumoxytol (Feraheme) • Ferric Derisomaltose (Monoferric)

General Background

Ferric Carboxymaltose Injection (Injectafer) is an iron replacement product indicated for the treatment of iron deficiency anemia (IDA) in adult patients who have intolerance to oral iron or have had unsatisfactory response to oral iron, and in adult patients with non-dialysis dependent chronic kidney disease (CKD). Each mL of Ferric Carboxymaltose Injection (FCM) contains 50 mg of elemental iron.[1]

Ferumoxytol (Feraheme) is indicated in adults for the treatment of iron deficiency anemia in patients who are intolerant to or have had an unsatisfactory response to oral iron and for the treatment of iron deficiency anemia in adult patients with chronic kidney disease. Each vial contains 510 mg of elemental iron in 17 mL (30 mg/mL).

Anaphylactic-type reactions, some of which have been life threatening and fatal, have been reported in patients receiving FCM. Patients may present with pruritus, rash, urticaria, wheezing, shock, clinically significant hypotension, loss of consciousness, and/or collapse. Patients should be monitored for signs and symptoms of hypersensitivity during and after FCM administration for at least 30 minutes and until clinically stable following completion of the infusion. Only administer FCM when personnel and therapies are immediately available for the treatment of serious hypersensitivity reactions. Serious anaphylactic/anaphylactoid reactions were reported in 0.1% who received FCM.[1]

Fatal and serious hypersensitivity reactions, including anaphylaxis, have occurred in patients receiving ferumoxytol. Initial symptoms may include hypotension, syncope, unresponsiveness, and cardiac or cardiorespiratory arrest. Only administer ferumoxytol as an intravenous infusion over at least 15 minutes and only when personnel and therapies are immediately available for the treatment of anaphylaxis and other hypersensitivity reactions. Observe for signs or symptoms of hypersensitivity reactions during and for at least 30 minutes following ferumoxytol infusion including monitoring of blood pressure and pulse during and after ferumoxytol administration. Hypersensitivity reactions have occurred in patients in whom a previous ferumoxytol dose was tolerated.

Of note, Medicare covers Sodium Ferric Gluconate Complex in Sucrose Injection and Iron Sucrose Injection as a first line treatment of IDA when furnished intravenously to patients undergoing chronic hemodialysis who are receiving supplemental erythropoietin therapy.[2]

Ferric Derisomaltose Injection (Monoferric) is an iron replacement product indicated for the treatment of iron deficiency anemia in adult patients who have an intolerance or unsatisfactory response to oral iron therapy or who have non-dialysis dependent chronic kidney disease. It is the first intravenous iron replacement product approved by the US FDA for the infusion of 1000 mg as a single dose in patients with iron deficiency anemia. Each mL of Ferric Derisomaltose Injection (FDM) contains 100 mg of elemental iron.[18]

Ferric Derisomaltose is contraindicated in patients who have experienced a serious or severe hypersensitivity reaction to ferric derisomaltose or any of its excipients. Reactions have included shock, clinically significant hypotension, loss of consciousness, and/or collapse. Ferric

Derisomaltose should not be administered to patients with iron overload as this could lead to excess iron stores and possibly to the development of iatrogenic hemosiderosis or hemochromatosis.[18]

Clinical Evidence

In a 35 day randomized, open-label, controlled clinical study, patients with iron deficiency anemia with inadequate response to oral iron during 14 day run-in period who received FCM had a significantly greater increase in hemoglobin (N = 244, mean change from baseline of 1.6g/dL) vs. patients who continued to receive oral iron (N = 251, mean change 0.8g/dL). Patients who were who were intolerant or inappropriate for oral iron who received FCM. The primary etiologies of iron deficiency anemia were heavy uterine bleeding (47%) and gastrointestinal disorders (17%).[3]

- In the 56 day REPAIR-IDA trial (N =2584), FCM was non-inferior to iron sucrose (Venofer, 5 doses up to 200 mg, maximum cumulative dose of 1000 mg) in achievement of increased Hgb (mean change from baseline Hgb 1.13 g/dL vs 0.92g/dL).2 No significant difference between treatment groups was found in the composite safety outcome, however, significantly more transient hypertensive episodes were observed in the FCM group than in the iron sucrose group (7.45% vs. 4.36%).[4]

- In a post-hoc analysis, significantly fewer patients who received FCM required retreatment between days 56 to 90 compared to iron sucrose (5.6% vs. 11.1%).[5]

- Of the 1775 in clinical studies of Injectafer, 75% were 65 years and over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients.[1]

- Compared with oral iron, ferumoxytol significantly increased mean Hb levels (0.82 to 1.2 mg/dL vs 0.16 to 0.5 mg/dL) and mean ferritin levels (233.93 to 381.7 nanogram/mL [ng/mL] vs 0.3 to 59.2 ng/mL) in patients with chronic kidney disease and iron deficiency anemia in three randomized trials. Mean transferrin saturation was also significantly increased (6.44% to 9.8% vs 0.3% to 1.3%). In two trials, the patients were nondialysis dependent with 36% to 42% using erythropoietin-stimulating agents (ESAs), and in the other trial, the patients were undergoing hemodialysis with 100% receiving ESAs

- A single alternative dose of ferumoxytol increased the mean Hb level by 2.6 g/dL at week 8 and was well tolerated during an observational study in patients with iron deficiency anemia and varied levels of baseline renal function (CrCl greater than 60, n=48; 31 to 60, n=5; 30 or less, n=7)

- In two large trials, ferumoxytol was non-inferior to iron sucrose and superior to placebo at achieving a 2 g/dL increase in Hb at any time from baseline to week 5 in patients with iron deficiency anemia and a history of intolerance or unsatisfactory response to oral iron therapy. Another large study demonstrated that ferumoxytol was non-inferior to ferric carboxymaltose with respect to the percentage of patients who experienced moderate-to-severe hypersensitivity reactions (including anaphylaxis) or moderate-to-severe hypotension. These adverse effects were reported less frequently in patients receiving ferumoxytol than with iron sucrose, but more frequently than with placebo.

- In an 8-week randomized, open-label, controlled clinical study FERWON-IDA trial (N = 1512), patients with IDA who had an intolerance to oral iron or unsatisfactory response to oral iron showed a statistically significant increase in hemoglobin of 2.49g/dL from baseline to week 8 in both the Monoferric and iron sucrose (Venofer) arms of the study. Non-inferiority was demonstrated for mean change in hemoglobin from baseline to week 8.[19]

- In an 8-week randomized, open-label, controlled clinical study FERWON-NEPHRO trial (N = 1538), patients with non-dialysis dependent chronic kidney disease who received Monoferric achieved a mean increase in hemoglobin from baseline to week 8 of 1.22g/dL versus a mean increase in hemoglobin from baseline to week 8 of 1.14g/dL in the iron sucrose (Venofer) group which confirmed non-inferiority.[20]

- In both the FERWON-IDA and FERWON-NEPHRO clinical trials combined; adverse reactions were reported in 8.6% of the patients treated with Monoferric and the most common adverse reactions reported were nausea (1.2%) and rash (1.0%).

Guideline from American Academy of Family Physicians on Iron Deficiency Anemia: Evaluation and Management (2013)[6]

• Diagnostic criteria for IDA may include many different laboratory studies and diagnosis is patient specific. Documentation should include symptoms of anemia and laboratory testing, such as complete blood count (CBC) including mean corpuscular volume (MCV), and iron studies (iron, ferritin, and total iron binding capacity (TIBC), transferrin saturation (TSAT). Among anemic patients with MCV < 95 µm3, a ferritin level < 30 ng/mL is considered diagnostic of iron deficiency; however, a ferritin level of 31 to 99 ng/mL remains predictive, and IDA may still be present. In those patients, if TIBC is increased with a decreased serum iron level and decreased TSAT, IDA is typically diagnosed. Soluble transferrin receptor level and/or erythrocyte protoporphyrin may also be assessed, if other iron studies are insufficient for diagnosis. The definitive diagnosis of IDA is absence of stainable iron in a bone marrow biopsy; however, this is an invasive procedure not routinely performed in clinical practice and only recommended if other tests are inconclusive with continued suspicion for IDA.

• Parenteral iron therapy should be considered for patients who cannot tolerate or absorb oral iron, such as those who have undergone gastrointestinal, bariatric, or small bowel surgeries, and with other comorbid conditions leading to malabsorption such as inflammatory bowel disease or celiac disease. Ongoing bleeding and anemia of chronic kidney failure are also common indications.

Causes and Diagnosis of Iron Deficiency and Iron Deficiency Anemia in Adults (Up-to-date)[7]

• Normal TSAT values are in the range of 25 to 45%. Values < 10% are common in individuals with IDA, and a cutoff of < 19% is generally used to screen for iron deficiency. (TSAT = serum iron ÷ TIBC x 100.) Low iron alone is not diagnostic of IDA as low iron levels may be present in anemia of chronic disease.

• Diagnosis of IDA is considered confirmed if anemia resolves upon iron administration.

Diagnosis of Iron Deficiency in Chronic Kidney Disease (Up-to-date)[8]

• Functional iron deficiency, characterized by adequate iron stores but insufficient iron availability for incorporation into erythroid precursors, is associated with administration of ESAs. The rate of iron release into circulation is too slow to keep up with the erythropoietic rate being driven by the ESAs.

• Absolute iron deficiency is likely present when TSAT ≤20 % and ferritin ≤100 ng/mL among nondialysis CKD or peritoneal dialysis patients or ≤200 ng/mL among hemodialysis patients.

• CKD patients may also have anemia of chronic disease, which is related to an underlying inflammatory state, causing falsely elevated ferritin levels.

• Both ESA-induced functional deficiency and anemia of chronic disease are characterized by TSAT that is commonly ≤20% and elevated ferritin levels as high as 800 ng/mL or even higher.

Kidney Disease: Improving Clinical Outcomes (KDIGO) 2012 Clinical Practice Guideline for Anemia in Chronic Kidney Disease[9]

• Diagnose anemia is all adults with CKD when Hgb concentration is < 13 g/dL in males and postmenopausal females and < 12 g/dL in premenopausal females.

• Ferritin < 30 ng/mL are indicative of severe iron deficiency, but if > 30 ng/mL, further studies of are needed to assess iron status.

• Iron deficiency should be corrected prior to initiation of ESA treatment.

• For adult CKD patients with anemia not on iron a trial of IV iron (or in non-dialysis CKD patients alternatively a 1–3 month trial of oral iron therapy) is suggested if: o an increase in Hgb concentration without starting ESA treatment is desired OR if on an ESA, a decrease in ESA dose is desired and o TSAT is < 30% and o ferritin is < 500 ng/ml

• For non-dialysis CKD patients who require iron supplementation, select the route of iron administration based on the severity of iron deficiency, availability of venous access, response to prior oral iron therapy, side effects with prior oral or IV iron therapy, patient compliance, and cost.

• Guide subsequent iron administration in CKD patients based on Hgb responses to recent iron therapy, as well as ongoing blood losses, iron status tests (TSAT and ferritin), Hgb concentration, ESA responsiveness and ESA dose.

• Evaluate iron status (TSAT and ferritin) at least every 3 months during ESA therapy, including the decision to start or continue iron therapy.

• Test iron status (TSAT and ferritin) more frequently when initiating or increasing ESA dose, when there is blood loss, when monitoring response after a course of IV iron, and in other circumstances where iron stores may become depleted.

• Untreated iron deficiency is a significant cause of insufficient response to ESA treatment.

National Kidney Foundation–Kidney Disease Outcomes Quality Initiative (NKF-KDOQI) Commentary on the 2012 KDIGO Clinical Practice Guideline for Anemia in CKD[10]

Among patients with CKD and anemia:

• There is insufficient evidence upon which to base a recommendation for an upper ferritin limit above which IV iron must be withheld

• There is insufficient evidence about whether IV iron should be withheld in patients with active infections; KDOQI makes no recommendation

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology: Cancer- and Chemotherapy- Induced Anemia[11]

In cancer patients:

• If absolute iron deficiency is present (ferritin < 30 ng/mL and transferrin saturation < 20%), consider IV or oral iron supplementation. Note: the ferritin value indicating iron deficiency is laboratory specific. In general, the lower the level of ferritin, the higher the probability that the patient has true iron deficiency anemia. However, in the cancer setting, be aware that a chronic inflammatory state may falsely elevate the serum ferritin. If with iron therapy, Hgb increases after 4 weeks, then observe with periodic re-evaluation for symptoms and risk factors; if Hgb does not increase after 4 weeks, consider functional iron deficiency

• If functional iron deficiency is present with those receiving ESAs (ferritin 30-500 ng/mL and TSAT <50%), consider IV iron supplementation

HCPCS Code

HCPCS Code	Description
Q0138	Injection, Ferumoxytol (Feraheme), 1 mg
J1439	Injection, Ferric Carboxymaltose (Injectafer), 1 mg
J1437	Injection, Ferric Derisomaltose(Monoferric), 10 mg

Acronyms

FCM = ferric carboxymaltose

FDM = ferric derisomaltose

Hgb = hemoglobin

IDA = iron deficiency anemia

CBC = complete blood count

MCV = mean corpuscular volume

TIBC = total iron binding capacity

TSAT = transferrin saturation

CKD = chronic kidney disease

ESRD = end stage renal disease

ESA = erythropoiesis-stimulating agent

NCD = National Coverage Determination

LCD = Local Coverage Determinations

FDA = Food and Drug Administration

KDIGO = Kidney Disease: Improving Clinical Outcomes

NKF-KDOQI = National Kidney Foundation Kidney Disease Outcomes Quality Initiative

NCCN = National Comprehensive Cancer Network

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