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MEDICAL POLICY – 5.01.630

Intravenous Iron Replacement Products

Effective Date:	May 1, 2025	RELATED MEDICAL POLICIES:
Last Revised:	Apr. 21, 2025	5.01.535 Erythropoiesis-Stimulating Agents
Replaces:	N/A	

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Introduction

Anemia is a condition in which the number of red blood cells (RBCs) or hemoglobin (Hgb) level in them is lower than normal. Hemoglobin is a protein that carries oxygen to the body's tissues. Some symptoms of anemia include fatigue, weakness, dizziness and shortness of breath. The optimal Hgb level needed to meet an individual's needs varies by age, sex, smoking habits, and pregnancy status. Common causes of anemia include nutritional deficiencies, chronic kidney disease (CKD), irritable bowel disease, and infectious diseases. Iron is needed to make red blood cells. Intravenous iron replacement is used in severe cases to quickly replace iron stores and reduce symptoms of anemia. This policy describes when intravenous iron replacement therapy for anemia may be considered medically necessary.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Intravenous Iron Replacement Products – First Line*

• Ferrlecit (sodium ferric gluconate complex); • Generic sodium ferric gluconate complex	• INFeD (iron dextran)	• Venofer (iron sucrose)
Intravenous Iron Replacement Products – Second Line		
• Feraheme (ferumoxytol); • Generic ferumoxytol	• Injectafer (ferric carboxymaltose)	• Monoferric (ferric derisomaltose)

*Preferred agents do not need preapproval for coverage.

Drug	Medical Necessity

Feraheme (ferumoxytol) IV,
Generic ferumoxytol IV
	Feraheme (ferumoxytol) and generic ferumoxytol may be considered medically necessary for iron deficiency anemia (IDA) in adults when the following criteria are met:
	• The individual is aged 18 years or older
	AND
	• Has either intolerance to oral iron or an inadequate response* to oral iron after at least 3 months of therapy
	  ○ **Exception:** No requirement for use of oral iron therapy for IDA in pregnancy or co-existing condition that would prevent absorption of oral iron therapy (e.g., gastric surgery or inflammatory bowel disease)
	OR
	• Has chronic kidney disease
	AND
	• Has either intolerance to or an inadequate response* with ≥ 1 of the following preferred IV iron products:
	  ○ Ferrlecit (sodium ferric gluconate complex)
	  ○ Generic sodium ferric gluconate complex
	  ○ INFeD (iron dextran)
	  ○ Venofer (iron sucrose)
	Note: *See **Appendix** for lab values associated with an inadequate response to iron therapy.

Injectafer (ferric carboxymaltose) IV	**Injectafer (ferric carboxymaltose) may be considered medically necessary for the treatment of iron deficiency anemia (IDA) when all the following criteria are met:**

Drug	Medical Necessity

	• The individual is aged 1 year or older with either intolerance to oral iron or an inadequate response* to oral iron after at least 3 months of therapy
	  ○ **Exception:** No requirement for use of oral iron therapy for IDA in pregnancy or co-existing condition that would prevent absorption of oral iron therapy (e.g., gastric surgery or inflammatory bowel disease)
	OR
	• The individual is aged 18 years or older with non-dialysis dependent chronic kidney disease
	OR
	• The individual is aged 18 years or older with chronic heart failure categorized as New York Heart Association (NYHA) class II or III with either intolerance to oral iron or an inadequate response* to oral iron after at least 3 months of therapy
	  ○ **Exception:** No requirement for use of oral iron therapy for IDA in pregnancy or co-existing condition that would prevent absorption of oral iron therapy (e.g., gastric surgery or inflammatory bowel disease)
	AND
	• Has either intolerance to or an inadequate response* with ≥ 1 of the following preferred IV iron products:
	  ○ Ferrlecit (sodium ferric gluconate complex)
	  ○ Generic sodium ferric gluconate complex
	  ○ INFeD (iron dextran)
	  ○ Venofer (iron sucrose)
	
	Note: *See **Appendix** for lab values associated with an inadequate response to iron therapy.

Monoferric (ferric derisomaltose) IV	**Monoferric (ferric derisomaltose) may be considered medically necessary for iron deficiency anemia (IDA) in adults when the following are met:** • The individual is aged 18 years or older **AND** • Has either intolerance to oral iron or an inadequate response* to oral iron after at least 3 months of therapy

Drug	Medical Necessity
	○ **Exception:** No requirement for use of oral iron therapy for IDA in pregnancy or co-existing condition that would prevent absorption of oral iron therapy (e.g., gastric surgery or inflammatory bowel disease **OR** • Has non-dialysis dependent chronic kidney disease **AND** • Has either intolerance to or an inadequate response* with ≥ 1 of the following preferred IV iron products: ○ Ferrlecit (sodium ferric gluconate complex) ○ Generic sodium ferric gluconate complex ○ INFeD (iron dextran) ○ Venofer (iron sucrose) **Note:** *See **Appendix** for lab values associated with an inadequate response to iron therapy.

Drug	Investigational
As listed	**All other uses of the above-named drugs when used in combination with each other or for conditions not FDA approved are considered investigational.** **The medications listed in this policy are subject to the product's US Food and Drug Administration (FDA) dosage and administration prescribing information.**

Length of Approval	
Approval	**Criteria**
Initial authorization	**Non-formulary exception reviews for all the drugs listed in this policy may be approved up to 12 months.** **All other reviews for all drugs listed in this policy may be approved up to 3 months.**
Re-authorization criteria	**Non-formulary exception reviews for all drugs listed in this policy may be approved up to 12 months in duration as long**

Length of Approval	
Approval	**Criteria**
	as the drug-specific coverage criteria are met, and chart notes include the following: • Documented positive response as shown by an increase in hemoglobin level of ≥1 g/dL from baseline **AND** • Laboratory results demonstrating need for additional therapy **All other reviews for all drugs listed in this policy may be approved up to 6 months in duration as long as the drug-specific coverage criteria are met, and chart notes include the following:** • Documented positive response as shown by an increase in hemoglobin level of ≥1 g/dL from baseline **AND** • Laboratory results demonstrating need for additional therapy

Documentation Requirements
The individual's medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following: • Office visit notes that contain the diagnosis, relevant history, physical evaluation and medication history

Coding

Code	Description
HCPC	
J1437	Injection, ferric derisomaltose (use to report: Monoferric), 10 mg
J1439	Injection, ferric carboxymaltose (use to report: Injectafer), 1 mg
Q0138	Injection, ferumoxytol, for treatment of iron deficiency anemia, (use to report: Feraheme), 1 mg (non-ESRD use)
Q0139	Injection, ferumoxytol, for treatment of iron deficiency anemia, (use to report: Feraheme), 1 mg (for ESRD on dialysis)

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

Consideration of Age

The ages stated in this policy for which Feraheme (ferumoxytol), generic ferumoxytol, Injectafer (ferric carboxymaltose), and Monoferric (ferric derisomaltose) are considered medically necessary are based on the ages approved in the US Food and Drug Administration (FDA) labeling.

Benefit Application

This policy is managed through the medical benefit.

Evidence Review

Background

Summary of Evidence

Efficacy of IV Iron

For the most part, the efficacy of IV iron formulations does not seem to appreciably differ; instead, approved indications, cost, number of doses required, and safety profile are more important factors for choice of one product over another. For instance, in the dialysis setting, frequency requirement for IV iron dosing is not as important as in the non-dialysis chronic kidney disease (CKD), gastrointestinal, obstetric, or heart failure iron deficiency anemia (IDA) settings. For the latter, it is much more convenient to receive a total dosing requirement in 1-2 infusions vs 5-8.

Safety of IV Iron

Intravenous iron products have evolved from historically poorly tolerated preparations to today's safer and effective agents. Early IV iron preparations were associated with serious toxic reactions caused by labile and rapid iron release. All of today's formulations of IV iron have a carbohydrate coating surrounding an elemental iron core and stronger carbohydrate-iron complex binding, which allows a slower release of iron. The newest carbohydrate moieties (carboxymaltose, ferumoxytol, and derisomaltose) are also purported to be less immunogenic, to lower risk of hypersensitivity reactions, although infrequent.

Hypersensitivity and Anaphylaxis

With today's IV iron products, anaphylaxis is a rare albeit unpredictable event. However, all IV iron products can cause typically mild to moderate infusion reactions (eg, flushing, itching, chest tightness, arthralgias, etc.). A 2020 meta-analysis of serious/severe hypersensitivity with the newer IV iron agents that included data from 21 prospective studies (9 head-to-head) and 8,599 individuals found ferric derisomaltose (Monoferric) to have fewer serious/severe hypersensitivity reactions overall compared to ferric carboxymaltose (Injectafer) or iron sucrose (Venofer). Although, there was no significant difference in anaphylaxis between the three comparators. In a 2022 retrospective cohort study using a target trial emulation framework and data from 167,925 Medicare individuals with part D coverage between July 2013 and December 2018 found adjusted rates of anaphylaxis per 10,000 first administrations were 9.8 cases (95% CI 6.2-15.3) for iron dextran, 4.0 cases (2.5-6.6) for ferumoxytol, 1.5 cases (0.3-6.6) for ferric gluconate, 1.2 cases (0.6-2.5) for iron sucrose, and 0.8 cases (0.3-2.6) for ferric carboxymaltose. Using iron sucrose as the reference, the adjusted odds ratios (ORs) for anaphylaxis were 8.3 (95% CI 3.5-19.8) for iron dextran and 3.4 (95% CI 1.4-8.3) for ferumoxytol. One significant limitation to the generalizability of these results is that the study only included Medicare individuals. Both iron dextran (INFeD) and ferumoxytol (Feraheme) carry boxed warnings for hypersensitivity and anaphylaxis, whereas other IV iron formulations do not.

Hypophosphatemia

Hypophosphatemia is an increasingly recognized issue with IV iron administration. The mechanism is believed to involve stimulation of fibroblast growth factor 23. Head-to-head trials show ferric carboxymaltose (Injectafer) is associated with a higher rate of hypophosphatemia compared to iron dextran, ferric derisomaltose (Monoferric) or ferumoxytol (Feraheme), including severe, symptomatic, and persistent hypophosphatemia (**Table 1**).

Table 1. Hypophosphatemia Comparative Ferric Carboxymaltose Trials

NCT No.	Trial Name	Comparator	Results
NCT01307007	Hypophosphatemia With Ferric Carboxymaltose Vs. Iron Dextran in Iron Deficiency Secondary to Heavy Uterine Bleeding	Iron dextran	Serum phosphate <2.0 mg/dL: 58.8% vs 0.0%
NCT02694978	A Phase III Safety Study of Ferumoxytol Compared to Ferric Carboxymaltose for the Treatment of Iron Deficiency Anemia (IDA)	Ferumoxytol	Serum phosphate <2.0 mg/dL: 50.8% vs 0.9% Severe <1.3 mg/dL: 10.0% vs 0.0%
NCT03238911 NCT03237065	Incidence of Hypophosphatemia After Treatment With Iron Isomaltoside/Ferric Derisomaltose vs Ferric Carboxymaltose in Subjects With Iron Deficiency Anaemia	Ferric derisomaltose	Serum phosphate <2.0 mg/dL: 74.4% vs 8.0% Severe ≤1.0 mg/dL: 11.3% vs 0.0%
NCT02905539	A Study Comparing the Iron Substitution With the Medicinal Products Ferinject or Monofer (HOMe_aFers_1)	Ferric derisomaltose	Serum phosphate <2.0 mg/dL: 75.0% vs 7.7%

Additionally, the results of a 2020 network meta-analysis performed to examine the comparative risk of hypophosphatemia following IV iron preparations from 8 randomized controlled trials including 5989 individuals showed ferric carboxymaltose (Injectafer) was associated with a significantly higher incidence of hypophosphatemia compared to ferric derisomaltose (Monoferric; risk ratio [RR] 7.90, 95% CI 2.10-28.0), iron sucrose (Venofer; RR 9.40, 95% CI 2.30-33.0), iron dextran (INFeD; RR 6.60, 95% CI 1.91-220.0), and ferumoxytol (Feraheme; RR 24.0, 95% CI: 2.50-220.0). No significant differences were estimated for the comparisons among ferric derisomaltose, iron sucrose, iron dextran, and ferumoxytol.

Cardiovascular Safety

No CV safety concerns have been reported in clinical trials for the newer IV iron products, ferric carboxymaltose (Injectafer), ferumoxytol (Feraheme), or ferric derisomaltose (Monoferric). Longer-term studies specifically evaluating the net clinical benefits of IV iron on CV endpoints have been limited to individuals with heart failure or end stage CKD receiving hemodialysis. No CV safety

signals were observed in the hemodialysis population, and higher doses of IV iron showed a benefit on CV endpoints compared with lower dose IV iron in the heart failure population. Large CV outcome trials for IV iron are ongoing (IRONMAN, FAIR-HF, and HEART-FID).

Infection and Other Adverse Events

A meta-analysis of epidemiological studies (n=15) and RCTs (n=7) did not support a higher risk of mortality, infection, cardiovascular events, or hospitalization from IV iron in individuals with HDD-CKD, although this conclusion is limited by small sample sizes, small event numbers, and statistical heterogeneity.

Ongoing and Unpublished Clinical Trials

Three large cardiovascular outcome trials for intravenous iron are ongoing and listed in **Table 2**.

Table 2. Summary of Key Trials

NCT No.	Trial Name	Enrollment	Completion Date
Ongoing			
NCT02642562	Intravenous Iron Treatment in Patients with Heart Failure and Iron Deficiency	1160	Aug 2022
NCT00520780	Ferinject Assessment in Patients with Iron Deficiency and Chronic Heart Failure	456	Sept 2009
NCT03037931	Randomized Placebo-controlled Trial of FCM as Treatment for Heart Failure with Iron Deficiency	3068	June 2023
NCT03036462	Intravenous Iron in Patients With Systolic Heart Failure and Iron Deficiency to Improve Morbidity & Mortality (FAIR-HF2)	1200	May 2024

NCT = National clinical trial, FCM = Ferric Carboxymaltose

Practice Guidelines and Position Statements

Kidney Disease Improving Global Outcomes (KDIGO) 2012

Adults with Chronic Kidney Disease (CKD) and anemia without erythropoietin stimulating agents (ESA)

IV iron (no product preference) or in NDD-CKD a 1-3 month oral iron trial if TSAT is ≤30% and ferritin is ≤500 ng/mL and not at goal.

Adults with CKD with ESA

IV iron (no product preference) or in NDD-CKD a 1-3 month oral iron trial if TSAT is ≤30% and ferritin is ≤500 ng/mL and not at goal.

Children with CKD and anemia without ESA

Oral iron (IV in HDD-CKD) if TSAT is ≤20% and ferritin is ≤100 ng/mL.

Children with CKD with ESA

Oral iron (IV in HDD-CKD) to maintain TSAT >20% and ferritin >100 ng/mL.

American Society for Clinical Oncology/American Society of Hematology (ASCO/ASH) 2019

Iron replacement may be used to improve Hgb response and reduce RBC transfusions for individuals receiving ESA therapy whether with or without iron deficiency.

2023 Update

Reviewed prescribing information for all drugs in policy and performed a literature search on the management of iron deficiency anemia. No new evidence found that would change this policy.

2024 Update

Reviewed prescribing information for all drugs in policy. Updated Injectafer (ferric carboxymaltose) to include coverage criteria for the treatment of certain adults with heart failure.

2025 Update

Reviewed prescribing information for all drugs in policy. Clarified that the medications listed in this policy are subject to the product's FDA dosage and administration prescribing information. Clarified that non-formulary exception review authorizations for all drugs listed in this policy may be approved up to 12 months.

Appendix

Laboratory values associated with inadequate response to iron therapy

Iron deficiency anemia without chronic kidney disease

- Children ≥ 6 months to < 5 years:
  - Ferritin < 15 ng/mL, **and/or**
  - Hemoglobin < 11 g/dL
- Children ≥ 5 to < 12 years:
  - Ferritin < 15 ng/mL, **and/or**
  - Hemoglobin < 11.5 g/dL
- Females ≥ 12 years (Nonpregnant):
  - Ferritin < 15 ng/mL, **and/or**
  - Hemoglobin < 12 g/dL
- Females ≥ 12 years (Pregnant):
  - Ferritin < 15 ng/mL, **and/or**

Laboratory values associated with inadequate response to iron therapy

Iron deficiency anemia without chronic kidney disease

- Hemoglobin < 11 g/dL
- Males ≥ 12 to < 15 years:
  - Ferritin < 15 ng/mL, **and/or**
  - Hemoglobin < 12 g/dL
- Males ≥ 15 years:
  - Ferritin < 15 ng/mL, **and/or**
  - Hemoglobin < 13 g/dL

Iron deficiency anemia with chronic kidney disease

- Adults with CKD:
  - TSAT is ≤ 30%, **and/or**
  - Ferritin is ≤ 500 ng/mL
- Pediatric individuals < 18 years of age with CKD:
  - TSAT is < 20%, **and/or**
  - Ferritin is ≤100 ng/mL

References

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History

Date	Comments
12/01/22	New policy, approved November 8, 2022, effective for dates of service on or after March 1, 2023, following 90-day provider notification. Add to Prescription Drug section. Added criteria for Feraheme (ferumoxytol), generic ferumoxytol, Injectafer (ferric carboxymaltose), and Monoferric (ferric derisomaltose) for the treatment of IDA. Added HCPC codes J1437, J1439, Q0138, & Q0139.
03/01/23	Policy implementation delayed; the effective date of the policy is moved to June 1, 2023.
12/01/23	Annual Review, approved November 20, 2023. No changes to policy statements.
04/01/24	Annual Review, approved March 12, 2024. Updated Injectafer (ferric carboxymaltose) to include coverage criteria for the treatment of certain adults with heart failure.
09/01/24	Coding update. Minor edit to parentheticals for HCPC codes Q0138 and Q0139.
05/01/25	Annual Review, approved April 21, 2025. Clarified that the medications listed in this policy are subject to the product's FDA dosage and administration prescribing information. Clarified that non-formulary exception review authorizations for all drugs listed in this policy may be approved up to 12 months.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member

benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.