

MEDICAL POLICY – 5.01.630


Intravenous Iron Replacement Products

Effective Date: May 1, 2025
Last Revised: Apr. 21, 2025
Replaces: N/A

RELATED MEDICAL POLICIES:
5.01.535 Erythropoiesis-Stimulating Agents

Select a hyperlink below to be directed to that section.

[POLICY CRITERIA](#) | [CODING](#) | [RELATED INFORMATION](#) | [EVIDENCE REVIEW](#) |
[REFERENCES](#) | [APPENDIX](#) | [HISTORY](#)

 Clicking this icon returns you to the hyperlinks menu above.

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*

| | | |
|---|--|---|
| <ul style="list-style-type: none"> Ferrlecit (sodium ferric gluconate complex); Generic sodium ferric gluconate complex | <ul style="list-style-type: none"> INFeD (iron dextran) | <ul style="list-style-type: none"> Venofer (iron sucrose) |
| Intravenous Iron Replacement Products – Second Line | | |
| <ul style="list-style-type: none"> Feraheme (ferumoxytol); Generic ferumoxytol | <ul style="list-style-type: none"> Injectafer (ferric carboxymaltose) | <ul style="list-style-type: none"> Monoferric (ferric derisomaltose) |

*Preferred agents do not need preapproval for coverage.

| Drug | Medical Necessity |
|--|--|
| Feraheme (ferumoxytol) IV, Generic ferumoxytol IV | <p>Feraheme (ferumoxytol) and generic ferumoxytol may be considered medically necessary for iron deficiency anemia (IDA) in adults when the following criteria are met:</p> <ul style="list-style-type: none"> The individual is aged 18 years or older <p>AND</p> <ul style="list-style-type: none"> Has either intolerance to oral iron or an inadequate response* to oral iron after at least 3 months of therapy <ul style="list-style-type: none"> 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) <p>OR</p> <ul style="list-style-type: none"> Has chronic kidney disease <p>AND</p> <ul style="list-style-type: none"> Has either intolerance to or an inadequate response* with ≥ 1 of the following preferred IV iron products: <ul style="list-style-type: none"> Ferrlecit (sodium ferric gluconate complex) Generic sodium ferric gluconate complex INFeD (iron dextran) Venofer (iron sucrose) <p>Note: *See Appendix for lab values associated with an inadequate response to iron therapy.</p> |
| Injectafer (ferric carboxymaltose) IV | <p>Injectafer (ferric carboxymaltose) may be considered medically necessary for the treatment of iron deficiency anemia (IDA) when all the following criteria are met:</p> |

| Drug | Medical Necessity |
|--|---|
| | <ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> 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) <p>OR</p> <ul style="list-style-type: none"> The individual is aged 18 years or older with non-dialysis dependent chronic kidney disease <p>OR</p> <ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> 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) <p>AND</p> <ul style="list-style-type: none"> Has either intolerance to or an inadequate response* with ≥ 1 of the following preferred IV iron products: <ul style="list-style-type: none"> Ferrlecit (sodium ferric gluconate complex) Generic sodium ferric gluconate complex INFeD (iron dextran) Venofer (iron sucrose) <p>Note: *See Appendix for lab values associated with an inadequate response to iron therapy.</p> |
| Monoferic (ferric derisomaltose) IV | <p>Monoferic (ferric derisomaltose) may be considered medically necessary for iron deficiency anemia (IDA) in adults when the following are met:</p> <ul style="list-style-type: none"> The individual is aged 18 years or older <p>AND</p> <ul style="list-style-type: none"> Has either intolerance to oral iron or an inadequate response* to oral iron after at least 3 months of therapy |

| Drug | Medical Necessity |
|------|---|
| | <ul style="list-style-type: none"> ○ 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) <p>OR</p> <ul style="list-style-type: none"> • Has non-dialysis dependent chronic kidney disease <p>AND</p> <ul style="list-style-type: none"> • Has either intolerance to or an inadequate response* with ≥ 1 of the following preferred IV iron products: <ul style="list-style-type: none"> ○ Ferrlecit (sodium ferric gluconate complex) ○ Generic sodium ferric gluconate complex ○ INFeD (iron dextran) ○ Venofer (iron sucrose) <p>Note: *See Appendix for lab values associated with an inadequate response to iron therapy.</p> |

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

| Length of Approval | |
|----------------------------------|--|
| Approval | Criteria |
| Initial authorization | <p>Non-formulary exception reviews for all the drugs listed in this policy may be approved up to 12 months.</p> <p>All other reviews for all drugs listed in this policy may be approved up to 3 months.</p> |
| 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 |
| | <p>as the drug-specific coverage criteria are met, and chart notes include the following:</p> <ul style="list-style-type: none"> Documented positive response as shown by an increase in hemoglobin level of ≥ 1 g/dL from baseline <p>AND</p> <ul style="list-style-type: none"> Laboratory results demonstrating need for additional therapy <p>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:</p> <ul style="list-style-type: none"> Documented positive response as shown by an increase in hemoglobin level of ≥ 1 g/dL from baseline <p>AND</p> <ul style="list-style-type: none"> Laboratory results demonstrating need for additional therapy |

| Documentation Requirements |
|--|
| <p>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:</p> <ul style="list-style-type: none"> 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 Monoferic (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 \leq 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 $\leq 30\%$ 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 $\leq 30\%$ 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 $\leq 20\%$ 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

1. Injectafer (ferric carboxymaltose injection) [product insert]. American Regent, Inc. Shirley, NY. Revised January 2025.
2. Feraheme (ferumoxytol injection) [product insert]. AMAG Pharmaceuticals, Inc. Waltham, MA. Revised June 2022.
3. Monoferic (ferric derisomaltose) [product insert]. Pharmacosmos Therapeutics Inc. Morristown, NJ. Revised August 2022.
4. Cohen J, Khudanyan A, Lu J, et al. A multicenter study evaluating the effectiveness and safety of single-dose low molecular weight iron dextran vs single-dose ferumoxytol for the treatment of iron deficiency. *Am J Hematol*. 2020;95(12):1572-1577.
5. Kosch M, Bahner U, Bettger H, Matzkies F, Teschner M, Schaefer RM. A randomized, controlled parallel-group trial on efficacy and safety of iron sucrose (Venofer) vs iron gluconate (Ferrelecit) in hemodialyses patients treated with rHuEpo. *Nephrol Dial Transplant*. 2001;16(6):1239-1244.
6. Sheashaa H, El-Huseini A, Sabry A, et al. Parenteral iron therapy in treatment of anemia in end-stage renal disease patients: a comparative study between iron saccharide and gluconate. *Nephron Clin Pract*. 2005;99(4):c97-101.
7. 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;29(4):833-842.
8. Macdougall IC, Strauss WE, McLaughlin J, Li Z, Dellanna F, Hertel J. A randomized comparison of ferumoxytol and iron sucrose for treating iron deficiency anemia in patients with CKD. *Clin Am J Soc Nephrol*. 2014;9(4):705-712.
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(5):683-690.



10. Bhandari S, Kalra PA, Berkowitz M, Belo D, Thomsen LL, Wolf M. Safety and efficacy of iron isomaltoside 1000/ferric derisomaltose versus iron sucrose in patients with chronic kidney disease: the FERWON-NEPHRO randomized, open-label comparative trial. *Nephrol Dial Transplant*. 2021;36(1):111-120.
11. Auerbach M, Henry D, Derman RJ, Achebe MM, Thomsen LL, Glaspy J. A prospective, multi-center, randomized comparison of iron isomaltoside 1000 versus iron sucrose in patients with iron deficiency anemia: the FERWON-IDA trial. *Am J Hematol*. 2019;94(9):1007-1014.
12. Kahn H, May P, Kuo E, et al. Safety and efficacy of a single total dose infusion (1020 mg) of ferumoxytol. *Ther Adv Hematol*. 2021;12:1-8.
13. Pollock RF, Biggar P. Indirect methods of comparison of the safety of ferric derisomaltose, iron sucrose, and ferric carboxymaltose in the treatment of iron deficiency anemia. *Expert Rev Hematol*. 2020;13(2):187-195.
14. Dave CV, Brittenham GM, Carson JL, Setoguchi S. Risks of anaphylaxis with intravenous iron formulations. *Ann Intern Med*. 2022;175:656-664.
15. Wolf M, Koch TA, Bregman DB. Effects of iron deficiency anemia and its treatment on fibroblast growth factor 23 and phosphate hemostasis in women. *J Bone Min Res*. 2013;28(8):1793-1803.
16. Wolf M, Rubin J, Achebe M, et al. Effects of iron maltoside vs ferric carboxymaltose on hypophosphatemia in iron deficiency anemia. *JAMA*. 2020;323(5):432-443.
17. Emrich IE, Lizzi F, Siegel JD, et al. Hypophosphatemia after high dosage iron substitution with ferric carboxymaltose and ferric derisomaltose --the randomized controlled HOME aFers study. *BMC Med*. 2020;18(1):178.
18. Blumenstein I, Shanbhag S, Langguth P, Kalra PA, Zoller H, Lim W. Newer formulations of intravenous iron: a review of their chemistry and their key safety aspects--hypersensitivity, hypophosphatemia, and cardiovascular safety. *Expert Opin Drug Safe*. 2021;20(7):757-769.
19. Hougen I, Collister D, Bourrier M, et al. Safety of intravenous iron in dialysis: a systematic review and meta-analysis. *Clin J Am Soc Nephrol*. 2018;13(3):457-467.
20. Bailie GR. Comparison of rates of reported adverse events associated with i.v. iron products in the United States. *Am J Health-Syst Pharm*. 2012;69:310-320.
21. Wang C, Graham DJ, Kane RC, et al. Comparative risk of anaphylactic reactions associated with intravenous iron products. *JAMA*. 2015;314(19):2062-2068.
22. Jesus-Silva JA, Lamplugh A, Dhada S, Burton JO, Bhandari S. Conversion of hemodialysis patients from iron sucrose to iron isomaltoside: a real-world experience. *BMC Nephrol*. 2020;21:212.
23. World Health Organization. Health topics: anemia. Available at: https://www.who.int/health-topics/anaemia#tab=tab_1. Accessed April 7, 2025.
24. Batchelor EK, Kapitsinou P, Pergola PE, Kovesdy CP, Jalal DI. Iron deficiency in chronic kidney disease: updates of pathophysiology, diagnosis, and treatment. *J Am Soc Nephrol*. 2020;31(3):456-468.
25. Kidney Disease Improving Global Outcomes. KDIGO clinical practice guideline for anemia in chronic kidney disease. *Kidney Int Suppl*. 2012;2(4):1-335. August 2, 2012.
26. Bohlius J, Bohlke K, Castelli R, et al. Management of cancer-associated anemia with erythropoiesis-stimulating agents: ASCO/ASH clinical practice guideline update. *J Clin Oncol*. 2019;37(15):1336-1351.
27. Choosing Wisely. American Society for Clinical Laboratory Science. Avoid using hemoglobin to evaluate patients for iron deficiency in susceptible populations. Instead, use ferritin. Released June 10, 2020. Available at: <https://www.choosingwisely.org/clinician-lists/ascls-avoid-using-hemoglobin-to-evaluate-patients-for-iron-deficiency-in-susceptible-populations-instead-use-ferritin/>. Accessed April 7, 2025.



28. WHO Guideline 1: Use of Ferritin Concentrations to Assess Iron Status in Individuals and Populations. Available at: https://cdn.who.int/media/docs/default-source/micronutrients/ferritin-guideline/ferritin-guidelines-executivesummary.pdf?sfvrsn=8c98babb_2_. Accessed April 7, 2025.
29. Powers J, Motil K, Drutz J. et al. Iron deficiency in infants and children <12 years: Screening, prevention, clinical manifestations, and diagnosis. UpToDate. Topic last updated: Oct 20, 2021.
30. Auerbach M, Means R, Elmore J, et al. Causes and diagnosis of iron deficiency and iron deficiency anemia in adults. UpToDate. Topic last updated: Jul 07, 2022.

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 Monoferic (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 parentheses 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. |

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2025 Premera All Rights Reserved.

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.

