Medical Policy Bulletin
Title:
Intravenous (IV) Iron Preparations
Policy #:
MA08.150

The Company makes decisions on coverage based on the Centers for Medicare and Medicaid Services (CMS) regulations and guidance, benefit plan documents and contracts, and the member's medical history and condition. If CMS does not have a position addressing a service, the Company makes decisions based on Company Policy Bulletins. Benefits may vary based on contract, and individual member benefits must be verified. The Company determines medical necessity only if the benefit exists and no contract exclusions are applicable. Although the Medicare Advantage Policy Bulletin is consistent with Medicare's regulations and guidance, the Company's payment methodology may differ from Medicare.

When services can be administered in various settings, the Company reserves the right to reimburse only those services that are furnished in the most appropriate and cost-effective setting that is appropriate to the member's medical needs and condition. This decision is based on the member's current medical condition and any required monitoring or additional services that may coincide with the delivery of this service.

This Policy Bulletin document describes the status of CMS coverage, medical terminology, and/or benefit plan documents and contracts at the time the document was developed. This Policy Bulletin will be reviewed regularly and be updated as Medicare changes their regulations and guidance, scientific and medical literature becomes available, and/or the benefit plan documents and/or contracts are changed.

Policy

Coverage is subject to the terms, conditions, and limitations of the member's Evidence of Coverage.

The Company reserves the right to reimburse only those services that are furnished in the most appropriate and cost-effective setting that is appropriate to the member's medical needs and condition.

Management of Heart Failure

The use of ferric carboxymaltose (Injectafer) for the treatment of adult individuals with New York Heart Association class II/III heart failure is considered medically necessary and, therefore, covered without the need to try any IV iron products to improve exercise capacity.

Management of Iron Deficiency (ID) or Iron Deficiency Anemia (IDA) Without Chronic Kidney Disease (CKD)

The use of an IV iron product, for the treatment of ID or IDA without CKD, is considered medically necessary and, therefore, covered for adult individuals with **ALL** of the following:

- Diagnosis of anemia based on hemoglobin (hgb) below normal levels for the individual's age and sex (if using to treat IDA)
- Ferritin level less than 30 ng/mL **OR** transferrin saturation (TSAT) less than 20 percent
- Normal kidney function as demonstrated by laboratory values (e.g., urine albumin, creatinine, glomerular filtration ratio [GFR])
- Documented intolerance, contraindication, or nonresponse to oral iron supplementation for at least 3 months

Management of Iron Deficiency (ID) or Iron Deficiency Anemia (IDA) With Chronic Kidney Disease (CKD)

The use of an IV iron product, for the treatment of ID or IDA with CKD, is considered medically necessary and, therefore, covered for adult individuals with **ALL** of the following:

- Diagnosis of anemia based on hgb below normal levels for individual's age and sex (if using to treat IDA)
- **ONE** of the following:
    - Ferritin level 100 ng/mL or less **AND** TSAT less than 20 percent in nondialysis individuals or those receiving peritoneal dialysis
    - Ferritin level 200 ng/mL or less **AND** TSAT less than 20 percent in individuals on hemodialysis
- CKD as demonstrated by abnormal laboratory values (e.g., urine albumin, creatinine, GFR)
- Documented intolerance, contraindication, or nonresponse to oral iron supplementation for at least 3 months

Management of Cancer- and Chemotherapy-Induced Anemia

The use of an IV iron product, for the treatment of cancer- and chemotherapy-induced anemia, is considered medically necessary and, therefore covered for adult individuals with **EITHER** of the following:

- For the treatment of **EITHER** of the following:
    - Absolute iron deficiency (ferritin <30 ng/mL and transferrin saturation <20 percent)
    - Possible functional iron deficiency (ferritin >500–800 ng/mL and transferrin saturation <50 percent) in selected individuals (with the goal of avoiding allogeneic transfusion)
- In combination with erythropoiesis-stimulating agents (ESAs) for the treatment of **EITHER** of the following:
    - Functional iron deficiency (ferritin 30–500 ng/mL and transferrin saturation <50 percent) in individuals receiving myelosuppressive chemotherapy without curative intent and ESAs
    - Absolute iron deficiency (ferritin <30 ng/mL and transferrin saturation <20 percent) in individuals who do not experience an increase in hemoglobin after 4 weeks of IV or oral iron supplementation

EXPERIMENTAL/INVESTIGATIONAL

All other uses for intravenous iron are considered experimental/investigational and, therefore, not covered unless the indication is supported as an accepted off-label use, as defined in the Company medical policy on off-label coverage for prescription drugs and biologics.

REQUIRED DOCUMENTATION

The individual's medical record must reflect the medical necessity for the care provided. These medical records may include, but are not limited to: records from the professional provider's office, hospital, nursing home, home health agencies, therapies, and test reports.

The Company may conduct reviews and audits of services to our members, regardless of the participation status of the provider. All documentation is to be available to the Company upon request. Failure to produce the requested information may result in a denial for the drug.

Guidelines

BLACK BOX WARNINGS

Refer to the specific manufacturer's prescribing information on ferumoxytol (Feraheme) and iron dextran (INFeD) for any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable Evidence of Coverage, intravenous iron is covered under the medical benefits of the Company's Medicare Advantage products when the medical necessity criteria listed in this medical policy are met.

US FOOD AND DRUG ADMINISTRATION (FDA) STATUS

Ferric carboxymaltose (Injectafer) was approved by the FDA on July 25, 2013 for the treatment of iron deficiency anemia in adult individuals who have intolerance to or have unsatisfactory response to oral iron or individuals who have non-dialysis dependent chronic kidney disease (CKD). Supplemental approvals for ferric carboxymaltose (Injectafer) have since been issued by the FDA.

Ferric derisomaltose (Monoferric) was approved by the FDA on January 16, 2020 for the treatment of iron deficiency anemia in adult individuals who have intolerance to or have had unsatisfactory response to oral iron or individuals who have non-hemodialysis dependent chronic kidney disease.

Ferumoxytol (Feraheme) was approved by the FDA on June 30, 2009 for the treatment of iron deficiency anemia (IDA) in adult individuals with chronic kidney disease (CKD). Supplemental approvals for ferumoxytol (Feraheme) have since been issued by the FDA.

Iron dextran (INFeD) was approved by the FDA on August 12, 2009 for the treatment of individuals with documented iron deficiency in whom oral administration is unsatisfactory or impossible. Supplemental approvals for iron dextran (INFeD) have since been issued by the FDA.

Iron sucrose (Venofer) was approved by the FDA on November 6, 2000 for the treatment of IDA in individuals undergoing chronic hemodialysis who are receiving supplemental erythropoietin therapy. Supplemental approvals for iron sucrose (Venofer) have since been issued by the FDA.

Sodium ferric gluconate complex in sucrose (Ferrlecit) was approved by the FDA on February 18, 1999 for the treatment of iron deficiency in individuals undergoing chronic hemodialysis who are receiving supplemental erythropoietin therapy. Supplemental approvals for sodium ferric gluconate complex in sucrose (Ferrlecit) have since been issued by the FDA.

PEDIATRIC USE
The safety and effectiveness of ferric carboxymaltose (Injectafer) in pediatric individuals less than 1 year of age with iron deficiency anemia have not been established.

The safety and effectiveness of ferric derisomaltose (Monoferric) in pediatric individuals have not been established.

The safety and effectiveness of ferumoxytol (Feraheme) in pediatric individuals less than 18 years old have not been established.

The safety and effectiveness of iron dextran (INFeD) in infants under 4 months of age have not been established. Iron dextran (INFeD) is not recommended for use in infants under 4 months of age.

The safety and effectiveness of iron sucrose (Venofer) for iron replacement treatment in pediatric individuals with dialysis and non-dialysis-dependent chronic kidney disease (CKD) have not been established.

The safety and effectiveness of sodium ferric gluconate complex in sucrose (Ferrlecit) have been established in pediatric individuals 6 to 15 years old, but have not been established in pediatric individuals younger than 6 years old.

BILLING GUIDELINES

Inclusion of a code in this policy does not imply reimbursement. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Description

Iron is absorbed from the gastrointestinal (GI) tract from food and stored in the liver in the form of ferritin. When needed by the body, the ferritin is released into the bone marrow to help make new red blood cells. When the red blood cells reach the end of their life cycle and undergo hemolysis, iron from those cells can be recycled and reused. If iron stores become depleted, either due to loss of blood, lack of adequate iron intake in the diet, or the lack of the body to absorb iron from the GI tract, iron-deficiency anemia (IDA) can occur. This can result in inadequate provision of oxygen to the body tissues and organs leading to multiple health issues. Although there can be other causes of anemia, IDA is the most common cause worldwide. The estimated prevalence of IDA in North America is 2.9 percent.

Common causes of IDA can include menstruation, pregnancy, breastfeeding, chronic kidney disease (CKD), major surgery, physical trauma, GI diseases (ulcerative colitis, Crohn's disease, celiac disease, peptic ulcer disease), GI malignancies, bariatric procedures, and vegetarian or vegan diets. There are multiple other less common causes of IDA as well. Efforts to identify and treat the cause(s) are necessary.

Blood tests are used to diagnose IDA. Results of laboratory tests will demonstrate the following: low hemoglobin (hgb), low mean cellular volume (MCV), low serum iron, low ferritin, low iron saturation, high transferrin, and high total iron-binding capacity (TIBC). When an individual is found to be anemic, as demonstrated by a low hgb, the next step is to look at the ferritin levels. There are different recommendations for the cut-off value for serum ferritin levels to define IDA proposed by different professional societies. The World Health Organization (WHO) recommends less than 12 ng/mL for healthy individuals under the age of 5 years, and less than 15 ng/mL for healthy individuals ages 5 years and above. For individuals with infection or inflammation, the levels increase to less than 30 ng/mL and less than 70 ng/mL for the same groups. The National Heart, Lung, and Blood Institute (NHLBI) recommend a cut-off level for ferritin at less than 10 ng/mL. The American Gastroenterological Association (AGA) recommends a cut-off level for ferritin at less than 45 ng/mL.

Once IDA has been identified, treatment can begin. Identifying the cause of the IDA can occur at the same time that the IDA is being treated. Treatment is usually begun with oral iron supplementation. If the individual is unable to tolerate oral iron supplementation, has a documented contraindication to oral iron supplementation, or has a documented nonresponse to oral iron supplementation, then erythropoiesis-stimulating agents (ESAs) and/or intravenous (IV) iron can be ordered. ESAs work by helping the bone marrow make more red blood cells (RBCs). Individuals who are on hemodialysis for end-stage renal disease (ESRD) can receive these medications while they are undergoing their dialysis treatments. If the anemia is severe enough that the individual has symptoms (e.g., fatigue, weakness, dizziness, lightheadedness), then the individual may require transfusions of blood products.

Ferric carboxymaltose (Injectafer) is a colloidal iron (III) hydroxide in complex with carboxymaltose, a carbohydrate polymer that releases iron.

Ferric derisomaltose (Monoferric) is a complex of iron (III) hydroxide and derisomaltose, an iron carbohydrate oligosaccharide that releases iron. Iron binds to transferrin for transport to erythroid precursor cells to be incorporated into hemoglobin.

Ferumoxytol (Feraheme) consists of a superparamagnetic iron oxide that is coated with a carbohydrate shell, which helps to isolate the bioactive iron from plasma components until the iron-carbohydrate complex enters the reticuloendothelial system macrophages of the liver, spleen, and bone marrow. The iron is released from the iron-carbohydrate complex within vesicles in the macrophages. Iron then either enters the intracellular storage iron pool (e.g., ferritin) or is transferred to plasma transferrin for transport to erythroid precursor cells for incorporation into hemoglobin.

Iron dextran (INFeD) is a complex of ferric hydroxide and dextran that releases iron into the circulation in order to replenish hemoglobin and depleted iron stores.

Iron sucrose (Venofer) is an aqueous complex of polynuclear iron (III) hydroxide in sucrose. Following intravenous administration, iron sucrose (Venofer) is dissociated into iron and sucrose and the iron is transported as a complex with transferrin to target cells including erythroid precursor cells. The iron in the precursor cells is incorporated into hemoglobin as the cells mature into red blood cells.

Sodium ferric gluconate complex in sucrose (Ferrlecit) is a stable macromolecular complex and is used to replete the body content of iron.

OFF-LABEL INDICATIONS

There may be additional indications contained in the Policy section of this document due to evaluation of criteria highlighted in the Company's off-label policy, and/or review of clinical guidelines issued by leading professional organizations and government entities.

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Coding

Inclusion of a code in this table does not imply reimbursement. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

The codes listed below are updated on a regular basis, in accordance with nationally accepted coding guidelines. Therefore, this policy applies to any and all future applicable coding changes, revisions, or updates.

In order to ensure optimal reimbursement, all health care services, devices, and pharmaceuticals should be reported using the billing codes and modifiers that most accurately represent the services rendered, unless otherwise directed by the Company.

The Coding Table lists any CPT, ICD-10, and HCPCS billing codes related only to the specific policy in which they appear.

CPT Procedure Code Number(s)
N/A

ICD - 10 Procedure Code Number(s)
N/A

ICD - 10 Diagnosis Code Number(s)
D50.9 Iron deficiency anemia, unspecified

D63.0 Anemia in neoplastic disease

D63.1 Anemia in chronic kidney disease

E61.1 Iron deficiency

I50.89 Other heart failure

I50.9 Heart failure, unspecified

HCPCS Level II Code Number(s)
J1437 Injection, ferric derisomaltose, 10 mg

J1439 Injection, ferric carboxymaltose, 1 mg

J1750 Injection, iron dextran, 50 mg

J1756 Injection, iron sucrose, 1 mg

J2916 Injection, sodium ferric gluconate complex in sucrose injection, 12.5 mg

Q0138 Injection, ferumoxytol, for treatment of iron deficiency anemia, 1 mg (non-ESRD use)

Q0139 Injection, ferumoxytol, for treatment of iron deficiency anemia, 1 mg (for ESRD on dialysis)

Revenue Code Number(s)

N/A

Policy History

Revisions From MA08.150:

12/15/2025	This policy will become effective 12/15/2025. This new policy has been developed to communicate the Company's coverage criteria for intravenous (IV) iron preparations.

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Version Reissued Date:
N/A