Intravenous Iron Products

Humana

Pharmacy Coverage Policy

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Line of Business: Medicaid - Louisiana
Policy Type: Prior Authorization

Products Affected

Feraheme intravenous solution
ferumoxytol intravenous solution
Injectafer intravenous solution
Monoferric intravenous solution

Listed Indications

Iron Deficiency Anemia

Iron Deficiency Anemia

Does the member meet all of the following criteria?	
Criteria #1	Member has a diagnosis of iron deficiency anemia
Criteria #2	Has had prior therapy, contraindication, or intolerance to Infed (iron dextran) and Venofer (iron sucrose)
Approval Duration	
Initial	Plan year duration or as determined through clinical review.

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Background

This is a prior authorization policy about Intravenous Iron Products (Feraheme/Ferumoxytol, Injectafer, Monoferric).
Feraheme (ferumoxytol), Injectafer (ferric carboxymaltose), and Monoferric (ferric derisomaltose) are intravenous iron replacement products indicated for the treatment of:

- iron deficiency anemia (IDA) in adults who have intolerance to oral iron or have had unsatisfactory response to oral iron
- IDA in pediatric patients 1 year of age and older who have either intolerance or an unsatisfactory response to oral iron [*Injectafer*]
- IDA in adults who have chronic kidney disease (CKD) [*Feraheme/Ferumoxytol*]
- IDA in adults who have non-dialysis dependent chronic kidney disease (CKD) [*Injectafer/Monoferric*]
- iron deficiency (ID) in adult patients with heart failure and New York Heart Association class II/III to improve exercise capacity [*Injectafer*]

Iron deficiency and Iron deficiency anemia
In 2013, the World Health Organization (WHO) identified iron deficiency (ID) as the leading cause of anemia among 1.93 billion people globally, making iron deficiency anemia (IDA) a major health issue. Total body iron is distributed among hemoglobin (Hb) in erythrocytes, myoglobin in muscles, iron-dependent proteins for cellular metabolism, and storage iron in the liver, spleen, and bone marrow. A small amount of iron is found in the circulation, bound to transferrin. Absolute ID reduces total body iron stores, while functional iron deficiency (FID) is an imbalance between iron demand and serum iron availability, occurring even with adequate body iron stores. ID can occur with or without anemia. Clinical symptoms of ID/IDA include alopecia, glossitis, pica, decreased cognitive abilities, fatigue, dyspnea, and syncope.

Effective management of ID/IDA involves identifying and treating the underlying cause. Intravenous iron (IVI) is often used when oral iron is ineffective, not tolerated, or when rapid iron replacement is needed. For patients with chronic kidney disease (CKD) and IDA who are not on dialysis, guidelines recommend either IVI or oral iron replacement. Patients with CKD and IDA who are dialysis-dependent should receive IVI. Patients with heart failure and reduced ejection fraction (HFrEF) are also recommended to receive IVI for treatment of IDA or ID. There is no specific guideline-recommended IVI product for any indication, but guidelines recommend single-dose infusion over multiple-dose infusions.

Black Box Warning (*FERAHEME/FERUMOXYTOL*): WARNING: RISK FOR SERIOUS HYPERSENSITIVITY/ANAPHLAXIS REACTIONS

Intravenous iron products are available as:

- Ferric carboxymaltose intravenous injection:
  - Injectafer single dose vial: 50mg/mL, 100mg/2mL, 750mg/15mL, 1000mg/20mL
- Ferric derisomaltose intravenous injection:
  - Monoferric single dose vial: 1000mg/10mL, 500mg/5mL, 100mg/mL
- Ferumoxytol intravenous injection:
  - Feraheme single dose vial: 510mg/17mL
  - Ferumoxytol single dose vial: 510mg/17mL

Recommended dosing and administration:

- Feraheme/Ferumoxytol:
  - Initial 510 mg dose followed by a second dose 3 to 8 days later
- Injectafer:
  - For patients weighing 50 kg or more: 750 mg IV in two doses separated by at least 7 days for a total cumulative dose of 1,500 mg of iron per course.
    - An alternative dose of 15 mg/kg body weight up to a maximum of 1,000 mm may be administered as a single-dose per course.
  - For patients weighing less than 50 kg: 15 mg/kg body weight IV in two doses separated by at least 7 days per course.
  - For patients with ID with Heart Failure: refer to package insert for weight-based dosing according to iron studies.
- Monoferric:
  - For patients weighing 50 kg or more: 1,000 mg IV.
  - For patients weighing less than 50 kg: 20 mg/kg actual body weight IV.
- Iron overload: regularly monitor hematologic responses during therapy. Do not administer to patients with iron overload.
- Hypersensitivity Reactions: Observe for signs and symptoms of hypersensitivity during and after administration for at least 30 minutes and until clinically stable following completion of each administration.
- Symptomatic Hypophosphatemia: Monitor serum phosphate levels in patients at risk for low serum phosphate who require a repeat course of treatment.
- Hypertension: Monitor patients closely for signs and symptoms of hypertension following each Injectafer administration
- Feraheme may cause hypotension. Monitor for signs and symptoms following each administration.

Please see product package insert(s) for complete boxed warning and full prescribing information.

Provider Claim Codes

For medically billed requests, please visit www.humana.com/PAL. Select applicable Preauthorization and Notification List(s) for medical and procedural coding information.

Medical Terms

Intravenous; iron; iron replacement; Feraheme; ferumoxytol; Injectafer; ferric carboxymaltose; Monoferric; ferric derisomaltose; pharmacy; iron deficiency anemia; chronic kidney disease; CKD; anemia

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