curative

Intravenous Iron Medical Policy

Drug(s) Applied:	**Ferrlecit** (Sodium ferric gluconate complex in sucrose) **INFeD** (Iron dextran) **Venofer** (Iron sucrose) **Feraheme/ ferumoxtyol** **Injectafer** (Ferric carboxymaltose)*

Criteria:
Curative considers Feraheme, ferumoxytol, Ferrlecit, INFeD, and Venofer to be preferred intravenous iron medications. All other intravenous iron products are considered not medically necessary including Injectafer*, Monoferric, and Triferic.
*For members who are pregnant, Injectafer will also be considered a preferred product.

Drug(s) Applied are considered medically necessary when the requested drug meets ALL the criteria below:

I. Initial Therapy Criteria
- **A. Iron deficiency anemia (IDA)** documented by chart notes within past 180 days, and ALL of the following:
  1. Diagnosis confirmed by ONE of the following:
     - a) IDA without chronic kidney disease (CKD) **and**
       - (1) ONE of the following labs within past 90 days:
         - (a) Serum ferritin less than 30 ng/mL **or**
         - (b) Transferrin saturation (TSAT) less than 20% **and**
       - (2) Patient has tried and had an unsatisfactory response or intolerance to oral iron (including daily and alternate-day dosing regimens), including any of the following:
         - (a) Failure of hemoglobin (Hb) to increase by >1 g/dL after 4 weeks of adherent oral iron therapy **or**
         - (b) Intolerance to oral iron characterized by significant GI side-effects (e.g., severe constipation, vomiting, diarrhea, etc.) **or**
         - (c) Patient is experiencing ongoing blood loss exceeding oral iron absorption capacity, such as active uterine bleeding and gynecological intervention is delayed **or**
         - (d) Diagnosis of gastrointestinal tract disorder, such as inflammatory bowel disease (ulcerative colitis and Crohn's

disease) **or**

(e) Patient has a malabsorption disorder (e.g., short bowel syndrome, allergic enteritis, etc.) **or**

(f) Patient has had gastric bypass surgery and/or subtotal gastric resection and has exhibited decreased absorption of oral iron **or**

b) IDA with non-dialysis CKD or CKD receiving peritoneal dialysis **and**

(1) Patient has ONE of the following labs within past 90 days:

(a) Serum ferritin less than 100 ng/mL and TSAT less than 40% **or**

(b) Serum ferritin between 100 ng/mL to 300 ng/mL and TSAT less than 25% **or**

(c) Serum ferritin less than or equal to 200 ng/mL and TSAT less than or equal to 20% **and**

(2) Patient has tried and had an unsatisfactory response or intolerance to oral iron (including daily and alternate-day dosing regimens), including any of the following:

(a) Failure of hemoglobin (Hb) to increase by >1 g/dL after 4 weeks of adherent oral iron therapy **or**

(b) Intolerance to oral iron characterized by significant GI side-effects (e.g., severe constipation, vomiting, diarrhea, etc.) **or**

(c) Patient is experiencing ongoing blood loss exceeding oral iron absorption capacity, such as active uterine bleeding and gynecological intervention is delayed **or**

(d) Diagnosis of gastrointestinal tract disorder, such as inflammatory bowel disease (ulcerative colitis and Crohn's disease) **or**

(e) Patient has a malabsorption disorder (e.g., short bowel syndrome, allergic enteritis, etc.) **or**

(f) Patient has had gastric bypass surgery and/or subtotal gastric resection and has exhibited decreased absorption of oral iron **or**

c) IDA with hemodialysis-dependent CKD and ONE of the following labs within the past 90 days:

(1) Serum ferritin less than or equal to 200 ng/mL and TSAT less than or equal to 20% **or**

(2) Serum ferritin less than or equal to 500 ng/mL and TSAT less than

or equal to 30% **or**

d) IDA with acute or chronic inflammatory conditions (e.g., heart failure, inflammatory bowel disease, rheumatologic autoimmune diseases) and ONE of the following labs within the past 90 days:
   (1) Serum ferritin less than 100 ng/mL **or**
   (2) Serum ferritin between 100-300 ng/mL and TSAT less than 20% **or**

e) IDA with cancer- or chemotherapy-induced anemia and ONE of the following labs within the past 90 days:
   (1) Absolute iron deficiency defined as serum ferritin less than 30 ng/mL and TSAT less than 20% **or**
   (2) Possible functional iron deficiency defined as serum ferritin between 500-800 ng/mL and TSAT less than 50% with the goal of avoiding allogeneic transfusion **or**
   (3) Functional iron deficiency defined as serum ferritin 30-500 ng/mL and TSAT less than 50% in those receiving myelosuppressive chemotherapy without curative intent and receiving an erythropoietin-stimulating agent (ESA) **and**

2. Patient's age is within FDA labeling for the requested indication or there is support for using the requested agent for the patient's age for the requested indication with ONE of the following:
   a) If for iron dextran (INFeD), patient must be at least 4 months of age **or**
   b) If for iron sucrose (Venofer), patient must be at least 2 years of age **or**
   c) If for ferric gluconate complex (Ferrlecit), patient must be at least 6 years of age **or**
   d) If for ferumoxytol (Feraheme), patient must be at least 18 years old **and**
3. If for ferric carboxymaltose (Injectafer), patient must be pregnant **and**
4. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., hematology)

Approval Duration: 3 months (1 course)

B. **Iron deficiency** documented by chart notes within past 180 days, and ALL of the following:
   1. Iron deficiency is confirmed by at least one of the following labs within past 90 days:
      a) Serum ferritin less than 30 ng/mL **or**
      b) TSAT <20% **and**
   2. Patient has tried and had an unsatisfactory response or intolerance to oral iron

(including daily and alternate-day dosing regimens), including any of the following:

a) Failure of hemoglobin (Hb) to increase by >1 g/dL after 4 weeks of adherent oral iron therapy **or**
b) Intolerance to oral iron characterized by significant GI side-effects (e.g., severe constipation, vomiting, diarrhea, etc.) **or**
c) Patient is experiencing ongoing blood loss exceeding oral iron absorption capacity, such as active uterine bleeding and gynecological intervention is delayed **or**
d) Diagnosis of gastrointestinal tract disorder, such as inflammatory bowel disease (ulcerative colitis and Crohn's disease) **or**
e) Patient has a malabsorption disorder (e.g., short bowel syndrome, allergic enteritis, etc.) **or**
f) Patient has had gastric bypass surgery and/or subtotal gastric resection and has exhibited decreased absorption of oral iron **and**

3. Patient's age is within FDA labeling for the requested indication or there is support for using the requested agent for the patient's age for the requested indication with ONE of the following:
   a) If for iron dextran (INFeD), patient must be at least 4 months of age **or**
   b) If for iron sucrose (Venofer), patient must be at least 2 years of age **or**
   c) If for ferric gluconate complex (Ferrlecit), patient must be at least 6 years of age **or**
   d) If for ferumoxytol (Feraheme), patient must be at least 18 years old **and**
4. If for ferric carboxymaltose (Injectafer), patient must be pregnant

Approval Duration: 3 months (1 course)

C. **Moderate to severe restless leg syndrome (RLS) with iron deficiency** documented by chart notes within past 180 days and ALL of the following:

1. Moderate to severe RLS with iron deficiency is confirmed by at least one of the following labs within past 90 days:
   a) Serum ferritin is less than or equal to 75 ng/mL **or**
   b) Serum ferritin is 75-300 ng/mL and TSAT less than 20% **and**
2. Patient has tried and had an unsatisfactory response or intolerance to oral iron (including daily and alternate-day dosing regimens), including any of the following:
   a) Failure of hemoglobin (Hb) to increase by >1 g/dL after 4 weeks of adherent oral iron therapy **or**
   b) Intolerance to oral iron characterized by significant GI side-effects (e.g.,

severe constipation, vomiting, diarrhea, etc.) **or**

c) Patient is experiencing ongoing blood loss exceeding oral iron absorption capacity, such as active uterine bleeding and gynecological intervention is delayed **or**

d) Diagnosis of gastrointestinal tract disorder, such as inflammatory bowel disease (ulcerative colitis and Crohn's disease) **or**

e) Patient has a malabsorption disorder (e.g., short bowel syndrome, allergic enteritis, etc.) **or**

f) Patient has had gastric bypass surgery and/or subtotal gastric resection and has exhibited decreased absorption of oral iron **and**

3. Patient's age is within FDA labeling for the requested indication or there is support for using the requested agent for the patient's age for the requested indication with ONE of the following:
   a) If for iron dextran (INFeD), patient must be at least 4 months of age **or**
   b) If for iron sucrose (Venofer), patient must be at least 2 years of age **or**
   c) If for ferric gluconate complex (Ferrlecit), patient must be at least 6 years of age **or**
   d) If for ferumoxytol (Feraheme), patient must be at least 18 years old **and**
4. If for ferric carboxymaltose (Injectafer), patient must be pregnant
   Approval Duration: 6 weeks (1 course)

D. **Iron-Refractory Iron Deficiency Anemia (IRIDA)** documented by chart notes within the past 180 days and ALL of the following:
   1. Genetic testing showing mutations in the TMPRSS6 gene **and**
   2. Patient has tried and had an unsatisfactory response or intolerance to oral iron (including daily and alternate-day dosing regimens), including ANY of the following:
      a) Failure of hemoglobin (Hb) to increase by >1 g/dL after 4 weeks of adherent oral iron therapy **or**
      b) Intolerance to oral iron characterized by significant GI side-effects (e.g., severe constipation, vomiting, diarrhea, etc.) **or**
      c) Patient is experiencing ongoing blood loss exceeding oral iron absorption capacity, such as active uterine bleeding and gynecological intervention is delayed **or**
      d) Diagnosis of gastrointestinal tract disorder, such as inflammatory bowel disease (ulcerative colitis and Crohn's disease) **or**
      e) Patient has a malabsorption disorder (e.g., short bowel syndrome, allergic enteritis, etc.) **or**

f) Patient has had gastric bypass surgery and/or subtotal gastric resection and has exhibited decreased absorption of oral iron **and**

3. Patient's age is within FDA labeling for the requested indication or there is support for using the requested agent for the patient's age for the requested indication with ONE of the following:
   a) If for iron dextran (INFeD), patient must be at least 4 months of age **or**
   b) If for iron sucrose (Venofer), patient must be at least 2 years of age **or**
   c) If for ferric gluconate complex (Ferrlecit), patient must be at least 6 years of age **or**
   d) If for ferumoxytol (Feraheme), patient must be at least 18 years old **and**
4. If for ferric carboxymaltose (Injectafer), patient must be pregnant **and**
5. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., hematology)

Approval Duration: 12 months

II. Continued Therapy Criteria

A. **Iron deficiency anemia (IDA)** documented by chart notes within past 180 days
   1. Patient meets the initial therapy criteria above

Approval Duration: 3 months (1 course). If for a malabsorption disorder, history of gastric bypass surgery and/or subtotal gastric resection, IDA due to hemodialysis-dependent CKD, or a chronic inflammatory condition with history of repeated need for IV iron, may approve up to 12 months.

B. **Iron deficiency** documented by chart notes within past 180 days
   1. Patient meets the initial therapy criteria above

Approval Duration: 3 months (1 course). If for a malabsorption disorder, history of gastric bypass surgery and/or subtotal gastric resection with history of repeated need for IV Iron, may approve up to 12 months.

C. **Moderate to severe restless leg syndrome (RLS) with iron deficiency** documented by chart notes within past 180 days
   1. Patient meets the initial therapy criteria above **and**
   2. Patient has had documented stabilization or improvement in RLS symptoms **and**
   3. If request is for INFeD, at least 12 weeks has elapsed since patient last received intravenous iron for the requested indication

Approval Duration: 6 weeks (1 course)

D. **Iron-Refractory Iron Deficiency Anemia (IRIDA)** documented by chart notes within

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past 180 days

1. Patient meets the initial therapy criteria above

Approval Duration: 12 months

Curative considers all other indications as experimental and investigational.

If submitting for medical billing:

J1750, iron dextran (INFeD), 1 unit = 50 mg
J1756, iron sucrose (Venofer), 1 unit = 1 mg
J2916, sodium ferric gluconate complex (Ferrlecit), 1 unit = 12.5 mg
Q0138, ferumoxytol (Feraheme), 1 unit = 1 mg
J1439, ferric carboxymaltose (Injectafer), 1 unit = 1 mg
96365, up to 1-hour IV infusion for non-chemotherapy (No PA required)
96366, additional time beyond first hour of IV infusion for non-chemotherapy (No PA required)