CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Arkansas PASSE

DRUG NAME	IV Iron Products
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Parenteral iron products include Injectafer (ferric carboxymaltose), Venofer (iron sucrose), Feraheme (ferumoxytol), Ferrlecit (sodium ferric gluconate), Infed (iron dextran), Monoferric (ferric derisomaltose), Triferic (ferric pyrophosphate), and Triferic AVNU (ferric pyrophosphate). All of the preparations are considered equally effective to raise hemoglobin. Triferic and Triferic AVNU are solely indicated for adults with hemodialysis dependent chronic kidney disease.
Iron deficiency anemia (IDA) is a type of microcytic anemia that occurs when low iron stores result in reduced erythropoiesis and decreased hemoglobin. There are a multitude of causative conditions for IDA such as malnutrition, malabsorption, inflammatory bowel disease (Crohn's disease or ulcerative colitis), chronic kidney disease, chronic heart failure, cancer, concomitant treatment with an erythropoiesis stimulating agent (ESA), pregnancy, and heavy bleeding. Iron deficiency replacement can be beneficial in chronic heart failure, with Injectafer being approved to improve exercise capacity in this group, whether or not anemia is present.

IV iron will be considered for coverage when the following criteria are met:

Iron Deficiency Anemia (IDA)

For **initial** authorization:

1. Member meets the labeled age for the respective product:
   a) Injectafer: at least 1 year of age
   b) Venofer: at least 2 years of age
   c) Feraheme: at least 18 years of age
   d) Ferrlecit: at least 6 years of age
   e) Infed: at least 4 months of age
   f) Monoferric: at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a nephrologist, gastroenterologist, OB/GYN, dietician, hematologist/oncologist, or cardiologist; AND
3. Member has a diagnosis of iron deficiency anemia with both of the following in the last 30 days:
   a) Hemoglobin <13 g/dL for male or <12 g/dL for female; <11 for pregnant female, <11 for age 0.5-5 years, <11.5 for age 5-12 years, <12 for age 12-15 years; AND
   b) Ferritin <100 ng/mL and/or TSAT (transferrin saturation) <20%; AND
4. Member meets one of the following:
   a) Inadequate response to 30 days of oral iron supplementation
   b) Documentation of intolerance to oral iron
   c) Not appropriate for oral iron (e.g., unable to swallow, blood loss too rapid for oral iron to compensate, severe anemia (Hb <8), history of gastric bypass surgery, active inflammatory bowel disease (i.e., Crohn's or UC), malabsorptive syndrome (e.g., celiac disease), concomitant use of an ESA, dialysis dependency); AND
5. For a non-preferred product request, inadequate response to at least 1 preferred alternative is required (Preferred products: Ferrlecit, Infed, Venofer).
6. **Dosage allowed/Quantity limit:**

Injectafer. Weight 50 kg or more: 750 mg IV in 2 doses separated by at least 7 days for a total dose of 1500 mg per course. For adults 50 kg or more, alternative option: 15 mg/kg up to 1000 mg as a single dose. Less than 50 kg: 15 mg/kg IV in 2 doses separated by at least 7 days. (QL: 30 mL per 28 days)
Venofer. Adult: 5 doses of 200 mg over 14 days. Pediatric (see package insert): 0.5 mg/kg, not to exceed 100 mg per dose. (QL: 5 vials per 28 days)
Feraheme. 510 mg dose followed by a second 510 mg dose 3 to 8 days later. (QL: 2 vials per 28 days)
Ferrlecit. Adults: 10 mL (125 mg of elemental iron) per dialysis session. (May require a cumulative dose of 1000 mg of elemental iron administered over 8 dialysis sessions). Pediatric: 1.5 mg/kg per dialysis session, not to exceed 125 mg per dose.
Infed. See table and formulas in package insert. Note: A test dose is required.
Monoferric. Weight 50 kg or more: 1000 mg as a single IV infusion. Less than 50 kg: 20 mg/kg as a single IV infusion. (QL: 10 mL per 28 days)

If all the above requirements are met, the medication will be approved for 3 months.

For **reauthorization**:
1. Chart notes/labs must show improvement of hemoglobin, ferritin, and/or TSAT; AND
2. Member continues to require iron replacement therapy, with no evidence of iron overload.

If all the above requirements are met, the medication will be approved for an additional 6 months.

Iron Deficiency with Heart Failure (Injectafer Only)

For **initial** authorization:
1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a cardiologist; AND
3. Member has a diagnosis of chronic heart failure with left ventricular ejection fraction of < 45% and New York Heart Association (NYHA) class II/III symptoms; AND
4. Member has a diagnosis of iron deficiency defined as serum ferritin <100 ng/mL or 100 to 300 ng/mL with TSAT <20%; AND
5. Member's hemoglobin is less than 15 g/dL; AND
6. Member's baseline 6-minute walk distance or another measure of exercise capacity is documented in chart notes (member must be ambulatory); AND
7. Member is on background therapy for heart failure.
8. **Dosage allowed/Quantity limit:**
   Administer IV on day 1 and at week 6 as below:

	Weight less than 70 kg			Weight 70 kg or more		
	Hb (g/dL)			Hb (g/dL)		
	< 10	10 to 14	> 14 to <15	< 10	10 to 14	> 14 to < 15
Day 1	1,000 mg	1,000 mg	500 mg	1,000 mg	1,000 mg	500 mg
Week 6	500 mg	No dose	No dose	1,000 mg	500 mg	No dose

Administer a maintenance dose of 500 mg at 12, 24 and 36 weeks if serum ferritin <100 ng/mL or serum ferritin 100-300 ng/mL with transferrin saturation <20% (see criteria for reauthorization).

If all the above requirements are met, the medication will be approved for 2 months.

For **reauthorization**:
1. Member's serum ferritin remains less than 100 ng/mL or 100-300 ng/mL with transferrin saturation <20%.

If all the above requirements are met, the medication will be approved for an additional 10 months.

Cancer- and chemotherapy-induced anemia

Any oncology related request must be submitted through NantHealth/Eviti portal.

CareSource considers IV iron not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
10/12/2022	New policy for IV iron products created.
08/24/2023	Added new indication for Injectafer for heart failure with iron deficiency. Corrected male/female hemoglobin cut offs in IDA section.
10/30/2023	Listed preferred products.

References:

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3. Feraheme [prescribing information]. AMAG Pharmaceuticals, Inc.; 2022.
4. Ferrlecit [prescribing information]. sanofi-aventis U.S. LLC; 2022.
5. Infed [prescribing information]. Allergan; 2021.
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19. Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines [published correction appears in Circulation. 2022 May 3;145(18):e1033] [published correction appears in Circulation. 2022 Sep 27;146(13):e185] [published correction appears in Circulation. 2023 Apr 4;147(14):e674]. *Circulation*. 2022;145(18):e895-e1032. doi:10.1161/CIR.0000000000001063

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