

PHARMACY POLICY STATEMENT

Indiana Medicaid

DRUG NAME	IV Iron Products
BILLING CODE	See appendix for code list
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.

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 <12 g/dL for male or <13 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.
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.

Monoferic. 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.

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.

Appendix I: Product names and billing codes

PRODUCT	CODE
Injectafer (ferric carboxymaltose)	J1439
Venofer (iron sucrose)	J1756
Feraheme (ferumoxytol)	Q0138
Ferrlecit (sodium ferric gluconate)	J2916
Infed (iron dextran)	J1750
Monoferic (ferric derisomaltose)	J1437
Triferic (ferric pyrophosphate)	J1443
Triferic AVNU (ferric pyrophosphate)	J1445

*Note: Triferic and Triferic AVNU are not specifically addressed in this policy because they are solely supported for use with hemodialysis.

References:

1. Injectafer [prescribing information]. American Regent, Inc.; 2022.

2. Venofer [prescribing information]. American Regent, Inc.; 2020.
3. Feraheme [prescribing information]. AMAG Pharmaceuticals, Inc.; 2022.
4. Ferrlecit [prescribing information]. sanofi-aventis U.S. LLC; 2022.
5. Infed [prescribing information]. Allergan; 2021.
6. Monoferric [prescribing information]. Pharmacosmos; 2022.
7. Triferic [prescribing information]. Rockwell Medical, Inc.; 2016
8. Triferic AVNU [prescribing information]. Rockwell Medical, Inc.; 2020.
9. Short MW, Domagalski JE. Iron deficiency anemia: evaluation and management. *Am Fam Physician*. 2013;87(2):98-104.
10. Camaschella C. Iron-deficiency anemia. *N Engl J Med*. 2015;372(19):1832-1843. doi:10.1056/NEJMra1401038
11. Camaschella C. Iron deficiency. *Blood*. 2019;133(1):30-39. doi:10.1182/blood-2018-05-815944
12. Numan S, Kaluza K. Systematic review of guidelines for the diagnosis and treatment of iron deficiency anemia using intravenous iron across multiple indications. *Curr Med Res Opin*. 2020;36(11):1769-1782. doi:10.1080/03007995.2020.1824898
13. Peyrin-Biroulet L, Williet N, Cacoub P. Guidelines on the diagnosis and treatment of iron deficiency across indications: a systematic review. *Am J Clin Nutr*. 2015;102(6):1585-1594. doi:10.3945/ajcn.114.103366
14. Snook J, Bhala N, Beales ILP, et al. British Society of Gastroenterology guidelines for the management of iron deficiency anaemia in adults. *Gut*. 2021;70(11):2030-2051. doi:10.1136/gutjnl-2021-325210
15. Ko CW, Siddique SM, Patel A, et al. AGA Clinical Practice Guidelines on the Gastrointestinal Evaluation of Iron Deficiency Anemia. *Gastroenterology*. 2020;159(3):1085-1094. doi:10.1053/j.gastro.2020.06.046
16. Dignass AU, Gasche C, Bettenworth D, et al. European consensus on the diagnosis and management of iron deficiency and anaemia in inflammatory bowel diseases. *J Crohns Colitis*. 2015;9(3):211-222. doi:10.1093/ecco-jcc/jju009
17. Klinger AS, Foley RN, Goldfarb DS, et al. KDOQI US commentary on the 2012 KDIGO Clinical Practice Guideline for Anemia in CKD. *Am J Kidney Dis*. 2013;62(5):849-859. doi:10.1053/j.ajkd.2013.06.008

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