THE OHIO STATE UNIVERSITY
HEALTH PLAN

Subject: Intravenous Iron Therapy **Revision Date**: 12/25

DESCRIPTION

Iron deficiency anemia (IDA) is most often caused by blood loss. However, IDA may also be the result of reduced iron absorption or redistribution after erythropoietin/erythropoiesis-stimulating agents. Treatment of the underlying cause in combination with oral iron supplementation is appropriate for most patients. Rarely, parenteral iron may be required. While parenteral iron provides a more rapid therapeutic response than oral iron, it can cause adverse effects including allergic reactions. Current parenteral iron preparations include:

- INFeD (iron dextran)
- Injectafer (ferric carboxymaltose)
- Feraheme (ferumoxytol)
- Ferrlecit (sodium ferric gluconate complex)
- Monoferric (ferric derisomaltose)
- Venofer (iron sucrose)

DEFINITIONS

Feraheme (ferumoxytol): Available as 510 mg iron per 17 mL (30 mg per mL) in single-dose vials. The recommended dose is an initial 510 mg dose followed by a second 510 mg dose 3 to 8 days later.

Ferrlecit (sodium ferric gluconate complex): Available as 62.5 mg/5 mL (12.5 mg/mL) in single-dose vials. The recommended dose for adults is 125 mg infused during each dialysis session. The recommended dose for pediatrics is 1.5 mg/kg infused during each dialysis session. Ferrlecit treatment may be repeated if iron deficiency reoccurs.

INFeD (iron dextran): Available as 100 mg/2 mL (50 mg/mL) in single-dose vials. The recommended

dose varies depending on the indication.

The dosing for anemia is based on the patient's weight and hemoglobin level. The following formula can be utilized to calculate the total dose for patients over 15 kg:

Dose (mL) = 0.0442 (Desired Hb – Observed Hb) x LBW + (0.26 x LBW)

Desired Hb = the target hemoglobin in g/dL

Observed Hb = the patient's current hemoglobin in g/dL

LBW = Lean body weight in kg [Males: LBW = 50 kg + 2.4 kg for each inch of patient's height over 5 feet; Females: LBW = 45.5 kg + 2.3 kg for each inch of patient's height over 5 feet.]

The following formula can be utilized to calculate the total dose for children 5 to 15 kg:

Dose (mL) = 0.0442 (Desired Hb – Observed Hb) x W + (0.26 x W)

Desired Hb = the target hemoglobin in g/dL
W = body weight in kg

No more than 2 mL of INFed should be administered per day. Daily doses should be given until the total required dose is administered.

The recommended dosage for blood loss is based on the approximate amount of blood loss and pretreatment hematocrit.

Dose (mL) = [Blood loss (in mL) x hematocrit] ÷ 50 mg/mL

Injectafer (ferric carboxymaltose): Available as 100 mg/2 mL, 750 mg/15 mL, and 1,000 mg/20 mL single-dose vials. The recommended dosage for iron deficiency anemia in patients weighing 50 kg or

more is 750 mg in two doses separated by at least 7 days for a total of 1,500 mg per course. For adults, a single dose of 15 mg/kg up to a maximum dose of 1,000 mg may be administered as an alternative. Persons weighing less than 50 kg should receive 15 mg/kg in two doses separated by at least 7 days per course. In patients with heart failure, this dose is modified based on weight and hemoglobin (g/dL). Additional maintenance doses of 500 mg at 12, 24, and 36 weeks is recommended for heart failure patients with a serum ferritin less than 100 ng/mL or between 100-300 ng/mL with a transferrin saturation less than 20%. Injectafer treatment can be repeated if iron deficiency reoccurs.

Monoferric (ferric derisomaltose): Available in 100 mg/mL, 500 mg/5 mL, and 1,000 mg/10 mL single-dose vials. The recommended dose for patients weighing 50 kg or more is 1,000 mg. The recommended dose for patients weighing less than 50 kg is 20 mg/kg. Repeat treatment if iron deficiency anemia reoccurs.

Venofer (iron sucrose): Available as 50 mg/2.5 mL, 100 mg/5 mL, and 200 mg/10 mL in single-dose vials. The recommended dose is based on the patient's age and diagnosis.

- Adult hemodialysis dependent on chronic kidney disease (HDD-CKD): 100 mg per infusion for a total treatment course of 1,000 mg.
- Adult non-dialysis dependent chronic kidney disease (NDD-CKD): 200 mg per infusion.
- Adult peritoneal dialysis dependent chronic kidney disease (PDD-CKD): 300 mg or 400 mg per infusion.
- Pediatric HDD-CKD maintenance treatment: 0.5 mg/kg, not to exceed 100 mg per dose, every 2 weeks for 12 weeks total.
- Pediatric PDD-CKD or NDD-CKD who are on erythropoietin therapy: 0.5 mg/kg, not to exceed 100 mg per dose, every 4 weeks for 12 weeks.

POLICY

The OSU Health Plan considers intravenous iron therapy medically necessary for covered persons with iron deficiency or iron deficiency anemia who meet all the following criteria:

- Presence of one or more of the following indications:
    - Cancer- and chemotherapy-induced anemia; or
    - Chronic kidney disease (CKD); or

- Congestive heart failure (CHF); or
- Contraindication to oral iron; or
- Need for rapid iron repletion (perioperative, pregnancy); or
- Inflammatory bowel disease (ulcerative colitis or Crohn's disease); or
- Failure of a 4-week trial of oral iron (intolerance or unsatisfactory response); or
- Gastric surgery (bypass or resection); or
- Malabsorption syndrome (celiac disease, Whipple's disease); or
- Ongoing blood loss that exceeds the capacity of oral iron to meet needs (e.g., heavy uterine bleeding); or
- Restless leg syndrome (RLS) and one or more of the following:
  - Malabsorption state
  - Intolerance to oral preparations
  - Moderate to severe symptoms despite trial of oral iron
- Unable to tolerate oral iron (Side effects must be documented by a physician and be severe in nature despite conservative interventions to manage symptoms. For example, constipation must persist despite an appropriate trial of stool softeners.); or
- Women in the second or third trimester who cannot tolerate oral iron or whose anemia did not improve with oral iron; or
- Women in the third trimester for whom there would be insufficient time to replete iron orally (after week 30)

- Laboratory values obtained within the last 30 days confirm diagnosis of iron deficiency:
  - Acute or chronic inflammatory condition:
    - Serum ferritin < 100 ng/ml; or
    - Transferrin saturation < 20%
  - Anemia from cancer or chemotherapy:
    - Serum ferritin < 30 ng/ml and transferrin saturation < 20%; or
    - Serum ferritin < 500 ng/ml and transferrin saturation < 50% in patients receiving an erythropoiesis-stimulating agent (ESA); or

        - Serum ferritin > 500 ng/mL and transferrin saturation < 50%
    - Chronic kidney disease (dialysis):
        - Serum ferritin ≤ 200 ng/ml and transferrin saturation ≤ 20%; or
        - Serum ferritin < 500 ng/ml, transferrin saturation ≤ 30%, and one or more of the following:
            - Hemoglobin < 10 g/dl; or
            - Patient is receiving an erythropoiesis-stimulating agent (ESA)
    - Chronic kidney disease (without dialysis):
        - Serum ferritin < 100 ng/ml; or
        - Transferrin saturation < 20%
    - Patients without chronic kidney disease or other comorbid condition:
        - Serum ferritin < 30 ng/ml; or
        - Transferrin saturation < 20%
    - Pregnancy:
        - Serum ferritin < 30 ng/mL; or
        - Transferrin saturation < 20%
    - Restless leg syndrome (RLS):
        - Serum ferritin ≤ 100 ng/ml and transferrin saturation < 45%

PROCEDURES

OSU Health Plan will cover intravenous iron therapy according to the above guidelines.

PRIOR AUTHORIZATION

Prior authorization is required for intravenous iron therapy. Refer to the Prior Authorization Guide at www.osuhealthplan.com.

EXCLUSIONS

Intravenous iron is contraindicated for patients with a history of an allergic reaction to any intravenous iron product.

There is a greater risk of anaphylaxis in patients with multiple drug allergies.

OSU Health Plan considers intravenous iron therapy experimental and investigational for all other indications including the following (not an all-inclusive list) because its clinical value for these indications has not been established:

- Acute mountain sickness
- Prophylactic use to improve function in non-anemic persons undergoing surgery for hip fracture.
- Prophylactic use to prevent postoperative anemia in persons undergoing bariatric surgery.
- Empiric treatment of restless legs syndrome when above criteria are not met.
- Treatment of post-operative anemia following major surgery (e.g., cardiothoracic surgery, colorectal cancer surgery, and neurosurgery)
- Pre-operative intravenous iron therapy for reduction of transfusions during major surgery
- Use in the first trimester of pregnancy.
- Infertility
- Prior to in vitro fertilization (IVF)
- Genetic hemochromatosis or hemochromatosis secondary to iron overload

Intravenous iron therapy for athletic performance is excluded from coverage according to the OSU Specific Plan Details (SPD).

CODES

HCPCS	Description
J1437	Injection, ferric derisomaltose, 10 mg
J1439	Injection, ferric carboxymaltose, 1 mg
J1443	Injection, ferric pyrophosphate citrate solution, 0.1 mg of iron
J1444	Injection, ferric pyrophosphate citrate powder, 0.1 mg of iron

J1445	Injection, ferric pyrophosphate citrate solution (Triferic AVNU), 0.1 mg of iron
J1750	Injection, iron dextran, 50 mg
J1756	Injection, iron sucrose, 1mg
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)

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