curative

TITLE:	IRON DEFICIENCY POLICY
POLICY #:	MM-PNP-015
VERSION #:	01
DEPARTMENT:	MEDICAL MANAGEMENT
ORIGINAL EFFECTIVE DATE:	10/1/2023
CURRENT REVISION DATE:	N/A

1. PURPOSE

Brand Selection for Medically Necessary Indications

Health care services are not medically necessary when they are more costly than alternative services that are at least as likely to produce equivalent therapeutic or diagnostic results. Feraheme (ferumoxytol injection) and Injectafer (ferric carboxymaltose injection) are more costly to Curative than other intravenous iron products (Ferrlecit (sodium ferric gluconate complex in sucrose injection), INFeD (iron dextran injection), and Venofer (iron sucrose injection) for certain indications.

There is a lack of reliable evidence that Feraheme (ferumoxytol injection) and Injectafer (ferric carboxymaltose injection) are superior to the lower cost intravenous iron products:

Therefore, Curative considers Feraheme (ferumoxytol injection) and Injectafer (ferric carboxymaltose injection) to be medically necessary only for members who have a contraindication, intolerance, or ineffective response to the available equivalent alternative intravenous iron products: Ferrlecit (sodium ferric gluconate complex in sucrose injection), INFeD (iron dextran injection), and Venofer (iron sucrose injection) for the labeled indication.

Note: If the less costly intravenous iron product does not have the labeled indication. Curative considers medically necessary another intravenous iron product that has the required labeled indication.

Iron-deficiency Anemia Associated with Peritoneal Dialysis and Non-Dialysis-Dependent (NDD) Chronic Kidney Disease

As defined in Curative commercial policies, health care services are not medically necessary when they are more costly than alternative services that are at least as likely to produce equivalent therapeutic or diagnostic results. Feraheme (ferumoxytol injection) is more costly to Curative than, Venofer (iron sucrose injection) for iron-deficiency anemia associated with peritoneal dialysis and non-dialysis-dependent (NDD) chronic kidney disease. There is a lack of reliable evidence that Feraheme (ferumoxytol injection) is superior to the lower cost intravenous iron product, Venofer (iron sucrose injection) for this indication. Therefore, Curative considers Feraheme (ferumoxytol injection) to be medically necessary only for members who have a contraindication, intolerance, or ineffective response to the available equivalent alternative intravenous iron product Venofer (iron sucrose injection) for iron-deficiency anemia associated with peritoneal dialysis and non-dialysis-dependent (NDD) chronic kidney disease.

2. SCOPE

Medical and Pharmacy UM Departments

3. DEFINITIONS

N/A

4. RESPONSIBILITIES

N/A

5. POLICY

Note: Requires Precertification:

Precertification of Ferrlecit (sodium ferric gluconate complex in sucrose injection), INFeD (iron dextran injection), and Venofer (iron sucrose injection) are required of all Curative participating providers and members in applicable plan designs.

Note: For the purposes of this policy, iron deficiency anemia (IDA) is defined as the following (unless otherwise specified in the policy):

- IDA without chronic kidney disease (CKD): serum ferritin less than 30 ng/dL or a transferrin saturation (TSAT) less than 20 percent confirms IDA.
- IDA with non-dialysis CKD: serum ferritin less than 100 ng/mL or TSAT less than 20 percent. If serum ferritin is 100-300 ng/mL, TSAT less than 20 percent is required to confirm IDA.
- IDA with hemodialysis-dependent CKD:
    - serum ferritin less than or equal to 200 ng/mL and TSAT less than or equal to 20 percent; *or*
    - serum ferritin less than 500 ng/mL and TSAT less than or equal to 30 percent and member has a hemoglobin less than 10 g/dL or is being treated with an erythropoiesis-stimulating agent (ESA).
- IDA with peritoneal dialysis-dependent CKD:
    - serum ferritin less than or equal to 100 ng/mL and TSAT less than or equal to 20 percent; or
    - serum ferritin is less than or equal to 500 ng/mL and TSAT less than or equal to 30 percent and the member has a hemoglobin less than 10 g/dL.
- IDA with acute or chronic inflammatory conditions: serum ferritin less than 100 ng/mL or TSAT less than 20 percent. If serum ferritin is 100-300 ng/mL, TSAT less than 20 percent is required to confirm iron deficiency.
- Cancer- and chemotherapy-induced anemia:
    - Absolute iron deficiency: serum ferritin less than 30 ng/mL and TSAT less than 20 percent; or
    - Possible functional iron deficiency: ferritin greater than 500-800 ng/mL and TSAT less than 50 percent; or
    - Functional iron deficiency in members receiving ESAs is defined as a serum ferritin 30-500 ng/mL and TSAT less than 50 percent.

Iron Dextran (INFeD)

Criteria for Initial Approval

Curative considers iron dextran (INFeD) intravenous iron therapy medically necessary for the following indications:

- Members 4 months of age and older who have documented iron deficiency with an unsatisfactory response, intolerance, or contraindication to oral iron administration alone or in *any* of the following scenarios:
    - Members who are losing iron (blood) at a rate too rapid for oral intake to compensate for the loss - this includes iron deficiency anemia due to heavy uterine bleeding, and members who are donating large amounts of blood for autologous programs; or
    - Members with a disorder of the gastrointestinal tract, such as inflammatory bowel disease (ulcerative colitis and Crohn's disease), in which symptoms may be aggravated by oral iron therapy; or
    - Members who repeatedly fail to heed instructions for oral iron supplementation or are incapable of accepting or following them; or
    - Members with iron deficiency following gastric bypass surgery and/or subtotal gastric resection and who exhibited decreased absorption of oral iron.
- Management of cancer- and chemotherapy-induced anemia when ***any*** of the following criteria are met:
    - For treatment of absolute iron deficiency (ferritin less than 30 ng/mL and TSAT less than 20 percent) with or without combination use with an erythropoiesis-stimulating agent (ESA); or
    - For treatment of possible functional iron deficiency (ferritin greater than 500-800 ng/mL and TSAT less than 50 percent) with the goal of avoiding allogeneic transfusion; or
    - For treatment of functional iron deficiency in combination with an ESA (ferritin 30-500 ng/mL and TSAT less than 50 percent) in members receiving myelosuppressive chemotherapy without curative intent.
- Treatment of members 18 years of age and older with moderate to severe restless leg syndrome (RLS) when ***all*** the following criteria are met:
    - Member’s serum ferritin is less than or equal to 100 ng/mL and TSAT is less than 45 percent; and
    - Member has an unsatisfactory response, intolerance, or contraindication to oral iron administration.

Continuation of Therapy

Curative considers continuation of iron dextran (INFeD) intravenous iron therapy medically necessary for members who meet criteria for an indication listed in Section I.

Iron Sucrose (Venofer)

Criteria for Initial Approval

Curative considers iron sucrose (Venofer) intravenous iron therapy medically necessary for the following indications:

- Member has documented iron deficiency anemia with an unsatisfactory response, intolerance, or contraindication to oral iron administration alone or in ***any*** of the following scenarios:
    - Members who are losing iron (blood) at a rate too rapid for oral intake to compensate for the loss - this includes iron deficiency anemia due to heavy uterine bleeding, and members who are donating large amounts of blood for autologous programs; or
    - Members with a disorder of the gastrointestinal tract, such as inflammatory bowel disease (ulcerative colitis and Crohn's disease), in which symptoms may be aggravated by oral iron therapy; or
    - Members who repeatedly fail to heed instructions for oral iron supplementation or are incapable of accepting or following them; or
    - Members with iron deficiency following gastric bypass surgery and/or subtotal gastric resection and who exhibited decreased absorption of oral iron.
    - Members 2 years of age and older who have documented iron deficiency anemia and a diagnosis of chronic kidney disease (CKD).
- Management of cancer- and chemotherapy-induced anemia when ***any*** of the following criteria are met:
    - For treatment of absolute iron deficiency (ferritin less than 30 ng/mL and TSAT less than 20 percent) with or without combination use with an erythropoiesis-stimulating agent (ESA); or
    - For treatment of possible functional iron deficiency (ferritin greater than 500-800 ng/mL and TSAT less than 50 percent) with the goal of avoiding allogeneic transfusion; or
    - For treatment of functional iron deficiency in combination with an ESA (ferritin 30-500 ng/mL and TSAT less than 50 percent) in members receiving myelosuppressive chemotherapy without curative intent.

Curative considers all other indications as experimental and investigational (for additional information, see Experimental and Investigational and Background sections).

Continuation of Therapy

Curative considers continuation of iron sucrose (Venofer) intravenous iron therapy medically necessary for members who meet criteria for an indication listed in Section I.

<u>Sodium Ferric Gluconate Complex (Ferrlecit)</u>

Criteria for Initial Approval

Curative considers sodium ferric gluconate complex (Ferrlecit) intravenous iron therapy medically necessary for the following indications:

- Member has documented iron deficiency anemia with an unsatisfactory response, intolerance, or contraindication to oral iron administration alone or in ***any*** of the following scenarios:
    - Members who are losing iron (blood) at a rate too rapid for oral intake to compensate for the loss. This includes iron deficiency anemia due to heavy uterine bleeding, and members who are donating large amounts of blood for autologous programs; or

  - Members with a disorder of the gastrointestinal tract, such as inflammatory bowel disease (ulcerative colitis and Crohn's disease), in which symptoms may be aggravated by oral iron therapy; or
  - Members who repeatedly fail to heed instructions for oral iron supplementation or are incapable of accepting or following them; or
  - Members with iron deficiency following gastric bypass surgery and/or subtotal gastric resection and who exhibited decreased absorption of oral iron.
  - Treatment of iron deficiency anemia in members 6 years of age and older with chronic kidney disease (CKD) receiving hemodialysis and who are receiving supplemental epoetin therapy (e.g., epoetin alpha, darbepoetin alfa).
- Management of cancer- and chemotherapy-induced anemia when ***any*** of the following criteria are met:
  - For treatment of absolute iron deficiency (ferritin less than 30 ng/mL and TSAT less than 20 percent) with or without combination use with an erythropoiesis-stimulating agent (ESA); or
  - For treatment of possible functional iron deficiency (ferritin greater than 500-800 ng/mL and TSAT less than 50 percent) with the goal of avoiding allogeneic transfusion; or
  - For treatment of functional iron deficiency in combination with an ESA (ferritin 30-500 ng/mL and TSAT less than 50 percent) in members receiving myelosuppressive chemotherapy without curative intent.

Curative considers all other indications as experimental and investigational (for additional information, see Experimental and Investigational and Background sections).

Continuation of Therapy

Curative considers continuation of sodium ferric gluconate complex (Ferrlecit) intravenous iron therapy medically necessary for members who meet criteria for an indication listed in Section I.

6. PROCEDURE

N/A

7. TRAINING REQUIREMENT

a. All Curative Medical and Pharmacy UM associates are responsible for reading and comprehending this procedure. Employees are also responsible for contacting management or Privacy and Compliance with any questions or concerns regarding the information contained within this procedure.

8. ENFORCEMENT

Violations of this controlled document will cause the imposition of sanctions in accordance with the Curative sanctions-controlled document. This may include verbal/written warning, suspension, up to termination of employment or volunteer, intern, contractor status with Curative. Additional civil, criminal, and equitable remedies may apply.

9. DOCUMENTATION

N/A

10. REFERENCE DOCUMENTS AND MATERIALS

N/A

11. COLLABORATING DEPARTMENTS

a. Medical and Pharmacy

12. DOCUMENT CONTROL

APPROVED BY:		
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(Printed Name)	**(Date)**	**(Signature)**

REVISION HISTORY			
Date	**Author**	**Version**	**Comments**
			Initial Version

APPENDICES

N/A