Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 345.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Intravenous (IV) Iron

Applicable line of business:

Commercial	X	Medicaid	
Medicare	X	ACA	X
CHIP	X		

I. Policy:
Intravenous (IV) Iron

II. Purpose/Objective:
To provide a policy of coverage regarding Intravenous Iron (ferric carboxymaltose (Injectafer), ferric derisomaltose (Monoferric), iron dextran complex (Infed), iron sucrose (Venofer), sodium ferric gluconate complex (Ferrlecit), ferumoxytol (Feraheme))

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:
a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

DESCRIPTION:
Iron dextran complex, iron sucrose, sodium ferric gluconate complex, ferumoxytol, ferric carboxymaltose and ferric derisomaltose are intravenous iron replacement products used to replete the body content of iron. Iron is critical for normal hemoglobin synthesis to maintain oxygen transport. Additionally, iron is necessary for metabolism and various enzymatic processes.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

NOTE: For commercial, exchange, and CHIP lines of business**, iron dextran complex (Infed), iron sucrose (Venofer), sodium ferric gluconate complex (Ferrlecit), ferumoxytol (Feraheme)** are preferred agents and DO NOT require prior authorization.

Ferric carboxymaltose (Injectafer) and ferric derisomaltose (Monoferric) require prior authorization and will be considered medically necessary for the commercial, exchange and CHIP lines of business when all of the following criteria are met:

- Medical record documentation of iron deficiency anemia as confirmed by ferritin <30 ng/ml no greater than 3 months old or transferrin saturation (TSAT) <20% no greater than 6 months old **AND**
- Medical record documentation that the member is age-appropriate to receive the intravenous iron medication based on the FDA-approved label **AND**
- One of the following:
    - Medical record documentation of failure on, intolerance to or contraindication to one (1) oral iron medication based on repeat iron labs completed after at least 4 weeks of oral iron administration

    OR
    - Medical record documentation that oral iron is medically inappropriate for the member*

AND
- Medical record documentation of failure on, intolerance to or contraindication to three (3) of the following: iron dextran complex (Infed), iron sucrose (Venofer), sodium ferric gluconate complex (Ferrlecit), ferumoxytol (Feraheme) **AND**
- Medical record documentation of a prescribed dose and administration that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature **AND**
- If a brand drug is being requested when a therapeutically equivalent generic drug exists:
    - Medical record documentation of a therapeutic failure of, or intolerance to the generic formulary agent(s) **OR**
    - Medical record documentation of an intolerance to or contraindication to the inactive ingredients of the generic formulary agent(s)

* Oral iron may not be medically appropriate for patients who have bleeding that is too great for oral iron to compensate, patients who have permanently impaired gastrointestinal absorption, patients who are in the second or third trimester of pregnancy, patients who do not tolerate oral iron, and patients who need surgery.

AUTHORIZATION DURATION: Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 6 months or less if the reviewing provider feels it is medically appropriate and will require:
- Medical record documentation of improvement from baseline but the member requires repeat treatment with IV iron **AND**
- Updated iron studies indicating ferritin <30 ng/ml no greater than 3 months old OR transferrin saturation (TSAT) <20% no greater than 6 months old.

The medication will no longer be covered if the patient experiences toxicity or worsening of disease

NOTE: For the Medicare line of business, **iron dextran complex (Infed), iron sucrose (Venofer), sodium ferric gluconate complex (Ferrlecit), ferumoxytol (Feraheme)** are preferred agents and DO NOT require Prior Authorization.

Ferric carboxymaltose (Injectafer) and ferric derisomaltose (Monoferric) require Prior Authorization and will be considered medically necessary for the Medicare line of business when all of the following criteria are met:

- Medical record documentation of iron deficiency anemia as confirmed by ferritin <30 ng/ml no greater than 3 months old or transferrin saturation (TSAT) <20% no greater than 6 months old **AND**
- Medical record documentation that the member is age-appropriate to receive the intravenous iron medication based on the FDA-approved label **AND**
- Medical record documentation of a prescribed dose and administration that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature **AND**
- Medical record documentation of failure on, intolerance to or contraindication to two (2) of the following: iron dextran complex (Infed), iron sucrose (Venofer), sodium ferric gluconate complex (Ferrlecit), ferumoxytol (Feraheme)

AUTHORIZATION DURATION: Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 6 months or less if the reviewing provider feels it is medically appropriate and will require:

- Medical record documentation of improvement from baseline but the member requires repeat treatment with IV iron **AND**
- Updated iron studies indicating ferritin <30 ng/ml no greater than 3 months old OR transferrin saturation (TSAT) <20% no greater than 6 months old.

The medication will no longer be covered if the patient experiences toxicity or worsening of disease.

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:

1. INFeD [prescribing information]. North Chicago, IL. AbbVie Inc.; August 2024.
2. Venofer [prescribing information]. Shirley, NY. American Regent Inc.; June 2022.
3. Ferrlecit [prescribing information]. Bridgewater, NJ. Sanofi-Aventis LLC; March 2022.
4. Feraheme [prescribing information]. Waltham, MA. AMAG Pharmaceuticals, Inc.; June 2022.
5. Injectafer [prescribing information]. Shirley, NY. American Regent, Inc.; January 2025.
6. Monoferric [prescribing information]. Morristown, NJ. Pharmacosmos Therapeutics Inc.; August 2022.
7. Auerbach, Michael, et al. “Iron Deficiency in Adults.” JAMA Network, 30 Mar. 2025, jamanetwork-com.geihsl.idm.oclc.org/journals/jama/fullarticle/2832131.

This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 5/13/25

Revised:

Reviewed:

MA UM Committee approval: 6/9/25