Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	May 6, 2022 December 2, 2022, May 2, 2023, July 20, 2023

Intravenous and Injectable Iron Agents

Preferred: Ferrlecit®, Sodium Ferric Gluconate Complex
Non-Preferred: Feraheme®, Ferumoxytol, Infed®, Injectafer®, Monoferric®, Triferic®, Venofer® **(refer to specific criteria)**

LENGTH OF AUTHORIZATION: Initial Therapy - 3 months
Continuation of therapy - 6 months

REVIEW CRITERIA:

- Medication requested must have a documented FDA approved indication and the patient must be within the FDA approved age limits.
- Patient is intolerant or had an unsatisfactory response to oral iron.
- Patient must have serum ferritin ≤ 300 ng/ml, transferrin saturation ≤ 20% and hemoglobin < 13 g/dl for men or < 12 g/dl for women *(baseline lab data drawn within 30 days of PA submission must be provided)*.
- Patients with Chronic Kidney Disease (CKD) on erythropoiesis stimulating therapy must have serum ferritin ≤ 500 ng/ml, transferrin saturation ≤ 30% and hemoglobin < 13 g/dl for men or < 12 g/dl for women *(baseline lab data drawn within 30 days of PA submission must be provided).*
- Hemodialysis dependent patients must have documented trial and failure on medications on the Preferred Drug List (PDL) or there is a reason (allergy, contraindication) that preferred drugs cannot be used.
- Non-hemodialysis dependent patients must have a trial on Infed before other non-preferred products can be considered.
- The requested medication's corresponding generic (if available) has been attempted and failed.

CONTINUATION OF THERAPY:

- Patient has met initial review criteria; **AND**
- Documentation of improved clinical response compared to baseline labs (supporting documentation and official lab results required); **AND**
- Patient has not experienced any treatment-restricting adverse effects; **AND**
- Dosing is appropriate as per labeling or is supported by compendia.

Venofer (iron sucrose):

Adult Patients

Initial Review Therapy

- Patient must be ≥ 18 years of age.
- Patient must have a documented diagnosis of iron deficiency anemia AND one of the following:
  - Hemodialysis Dependent CKD
  - Non-Dialysis Dependent CKD
  - Peritoneal Dialysis Dependent CKD

- Pregnancy

- The patient must have documented trial and failure on medications on the PDL or there is a reason (allergy, contraindication) that preferred drugs cannot be used.
- Patient must have serum ferritin ≤ 300 ng/ml, transferrin saturation ≤ 20% and hemoglobin < 13 g/dl for men or < 12 g/dl for women *(baseline lab data drawn within 30 days of PA submission must be provided)*.
- Patients with CKD on erythropoiesis stimulating therapy must have serum ferritin ≤ 500 ng/ml, transferrin saturation ≤ 30%, and hemoglobin <12 g/dl *(lab data drawn within 30 days of PA submission must be provided).*

Pediatric Patients

Initial Review Criteria

- Patient must be ≥ 2 years of age.
- Patient must have a documented diagnosis of iron deficiency anemia AND one of the following:
  - Hemodialysis Dependent CKD
  - Non-Dialysis Dependent CKD
  - Peritoneal Dialysis Dependent CKD receiving concurrent erythropoiesis stimulating therapy
- The patient must have documented trial and failure on medications on the PDL or there is a reason (allergy, contraindication) that preferred drugs cannot be used.
- Patient must have serum ferritin ≤ 300 ng/ml and transferrin saturation ≤ 20% for Hemodialysis Dependent CKD, Non-Dialysis Dependent CKD and hemoglobin < 12 g/dl *(baseline lab data drawn within 30 days of PA submission must be provided).*
- Patient must have serum ferritin ≤ 500 ng/ml and transferrin saturation ≤ 30% for Peritoneal Dependent CKD *(baseline lab data drawn within 30 days of PA submission must be provided).*

CONTINUATION OF THERAPY:

- Patient meets initial review criteria; **AND**
- Documentation of improved clinical response compared to baseline labs (supporting documentation and official lab results required); **AND**
- Patient has not experienced any treatment-restricting adverse effects; **AND**
- Dosing is appropriate as per labeling or is supported by compendia.

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/