



Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	May 6, 2022

## Intravenous and Injectable Iron Agents

**Preferred:** Ferrlecit<sup>®</sup>, Sodium Ferric Gluconate Complex

**Non-Preferred:** Feraheme<sup>®</sup>, Ferumoxytol, Infed<sup>®</sup>, Injectafer<sup>®</sup>, Monoferric<sup>®</sup>, Triferic<sup>®</sup>, Venofer<sup>®</sup> (**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  $\leq 300$  ng/ml and transferrin saturation  $\leq 20\%$  (*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  $\leq 500$  ng/ml and transferrin saturation  $\leq 30\%$  (*baseline lab data drawn within 30 days of PA submission must be provided*).
- The patient 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.
- 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  $\geq 18$  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



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- 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  $\leq 300$  ng/ml and transferrin saturation  $\leq 20\%$  (*lab data drawn within 30 days of PA submission must be provided*).
- Patients with CKD on erythropoiesis stimulating therapy must have serum ferritin  $\leq 500$  ng/ml and transferrin saturation  $\leq 30\%$  (*lab data drawn within 30 days of PA submission must be provided*)

### Pediatric Patients

#### **Initial Review Criteria**

- Patient must be  $\geq 2$  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  $\leq 300$  ng/ml and transferrin saturation  $\leq 20\%$  for Hemodialysis Dependent CKD and Non-Dialysis Dependent CKD (*baseline lab data drawn within 30 days of PA submission must be provided*).
- Patient must have serum ferritin  $\leq 500$  ng/ml and transferrin saturation  $\leq 30\%$  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/>