ATRIO HEALTH PLANS

Iron Salt Drugs

Preferred: Oral Iron Supplements (Ferrous Sulfate, Ferrous Gluconate, Ferrous Fumarate, etc)
Preferred: INFed (Iron Dextran) J1750**, Venofer** (Iron Sucrose) J1756, **Ferrlecit** (Sodium Ferric Gluconate Complex) J2916

Non-preferred: Monoferric (Ferric Derisomaltose inj) J1437**, Injectafer** (Ferric Carboxymaltose) J1439**, Triferic** (Ferric Pyrophosphate) J1443**, Feraheme** (Ferumoxytol inj for NON-ESRD) Q0138**, Feraheme** (Ferumoxytol inj for ESRD) Q0139

Prior Authorization Step Therapy **Medicare Part B Request Form**

*Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

☐	**Standard Request– (72 Hours)**	☐	**Urgent Request** (**24 Hours** - standard time frame could place the member's life, health or ability in serious jeopardy)
	Date Requested: _____		
	Requestor: _____ Clinic name: _____ Phone:_____ Fax:_____		

MEMBER INFORMATION

*Name:_____ *ID#:_____ *DOB:_____

PRESCRIBER INFORMATION

*Name:_____ ☐MD ☐FNP ☐DO ☐NP ☐PA *Phone:_____

*Address:_____ *Fax:_____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name:_____ Phone:_____

*Address:_____ Fax:_____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht:_____)	Frequency	End Date (if known)

☐ **Self-administered** ☐ **Provider-administered** ☐ **Home Infusion**

☐Chart notes attached. **Other important information:**_____

Diagnosis (ICD10): _____ **Description**: _____

☐ Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

STEP THERAPY

☐ **Iron Deficiency Anemia**

☐ Preferred:
Oral Iron Supplements **(No PA Required)** THEN
Injectable Iron Supplements **(No PA Required)**: ☐ INFed ☐ Venofer ☐ Ferrlecit
☐ Patient has tried and failed at least 3 months of Oral Iron Supplements

☐ Non-Preferred: **(PA REQUIRED)**
☐ Monoferric ☐ Injectafer ☐ Triferic ☐ Feraheme(ESRD) ☐ Feraheme(Non-ESRD)
☐ Member has tried/failed AT LEAST 3 months of an injectable Preferred alternative

☐ New Start or Initial Request: (Clinical documentation required for all requests)

☐ Patient has a diagnosis of chronic kidney disease (CKD); AND
- ☐ Patient is dialysis dependent; AND
- ☐ Patient has iron deficiency anemia (IDA);

☐ Patient has a diagnosis of iron deficiency anemia (IDA); AND
- ☐ Patient is non-dialysis dependent;
- ☐ Diagnosis is confirmed by one of the following:
- ☐ For IDA associated with CKD or inflammatory conditions (for example, inflammatory bowel disease [IBD], heart failure), Patient meets one of the following within the last four (4) weeks:
  - ☐ Serum ferritin levels less than 100 ng/mL; OR
  - ☐ TSAT levels less than 20%; OR
  - ☐ Serum ferritin is less than or equal to 500 ng/mL and TSAT is less than or equal to 30% OR
  - ☐ Bone marrow demonstrates inadequate iron stores; OR
  - ☐ Hemoglobin (HGB) less than 13 g/dl (less than 130 g/l) in males or less than 12 g/dl (less than 120g/l) in females and TSAT 30% or less and ferritin 500ng/ml or less (500 µg/l or less) (Ko 2020);
- ☐ For IDA associated with cancer/chemotherapy or non-inflammatory conditions (for example, blood loss, malabsorption, malnutrition), Patient meets one of the following within the last four (4) weeks:
  - ☐ Serum ferritin levels less than 30 ng/mL; OR
  - ☐ TSAT levels less than 20%; OR
  - ☐ Bone marrow demonstrates inadequate iron stores; AND
- ☐ Patient had a four (4) week trial of and inadequate response, or intolerance to oral iron supplementation; OR
- ☐ Patient is unable to use oral iron supplementation for one of the following reasons:
  - ☐ Malabsorption conditions; OR
  - ☐ Gastric Surgery;

☐ Patient has iron deficiency anemia in pregnancy;
- ☐ Diagnosis is confirmed by one of the following:
  - ☐ Serum ferritin levels less than 30 ng/mL; OR
  - ☐ TSAT levels less than 20%; OR
  - ☐ Bone marrow demonstrates inadequate iron stores; AND
- ☐ Patient is past 14 weeks of pregnancy and has had a four (4) week trial of and inadequate response, or intolerance to oral iron supplementation (Muñoz 2017); OR
- ☐ Patient is past 14 weeks of pregnancy and diagnosed with severe iron deficiency anemia, defined as Hemoglobin (HGB) less than 8 g/dL; OR
- ☐ Patient is past 34 weeks of pregnancy.

If not, please provide **clinical rationale** for formulary exception: _____

☐ Continuation Requests: (Clinical documentation required for all requests)

☐ Patient has received the requested product in the past 365 days**.**

☐ Patient had an adequate response or significant improvement while on this medication.

If not, please provide clinical rationale for continuing this medication: _____

_____

ACKNOWLEDGEMENT

Request By (Signature Required): _____Date:_____ /____ /____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties.

THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT. PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – Ophthalmic VEGF Inhibitors PA

Drug Name(s):

FERAHEME	**FERUMOXYTOL**
INJECTAFER	**FERRIC CARBOXYMALTOSE**
TRIFERIC	**FERRIC PYROPHOSPHATE**
MONOFERRIC	**DERISOMALTOSE**
INFED	**IRON DEXTRAM**
VENOFER	**IRON SUCROSE**
FERRLICIT	**SODIUM FERRIC GLUCONATE COMPLEX**

Criteria for approval of Prior Authorization Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.

- If the member meets all these criteria, they may be approved by the Plan for the requested drug.
- Quantity limits and Tiering will be determined by the Plan, in accordance with the Label.

Exclusion Criteria:

N/A

Prescriber Restrictions:

N/A

Coverage Duration:

Approvals will be for 12 months

FDA Indications:

Feraheme, Injectafer, InFed, Monoferric

- Chronic kidney disease - Iron deficiency anemia (Injectafer, Monoferic: only for nondialysis dependent)
- Iron deficiency, Due to blood loss (InFed only)
- Heart failure, NYHA class II/III to improve exercise capacity - Iron deficiency (Injectafer only)
- Iron deficiency anemia, Intolerant or unsatisfactory response to oral iron

Ferrlecit

- Hemodialysis - Iron deficiency anemia, During epoetin therapy

Venofer

- Chronic kidney disease - Iron deficiency anemia

Triferic

- Dependence on hemodialysis due to end stage renal disease - Iron deficiency anemia

Off-Label Uses:

INFed

- Anemia due to and following chemotherapy, In combination with an erythropoiesis-stimulating agent
- Chronic kidney disease, non-dialysis dependent - Iron deficiency anemia, with or without erythropoietin
- Chronic kidney disease - Hemodialysis - Iron deficiency anemia, in patients receiving erythropoietin
- Chronic kidney disease - Iron deficiency anemia, in patients receiving erythropoietin - Peritoneal dialysis
- Iron deficiency anemia of pregnancy
- Restless legs syndrome

Injectafer, Venofer

- Iron deficiency anemia of pregnancy
- Restless legs syndrome (Injectafer)

Feraheme

- Restless legs syndrome

Ferrlecit

- Anemia due to and following chemotherapy, In combination with an erythropoiesis-stimulating agent
- Iron deficiency anemia of pregnancy

Age Restrictions:

Safety and efficacy have not been established in pediatric patients

Other Clinical Considerations:

N/A

Resources:

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