Iron Salt Drugs

Monoferric (ferric derisomaltose) J1437, Feraheme (ferumoxytol) Q0138, Q0139, Injectafer (ferric carboxymaltose) J1439, Triferic (ferric pyrophosphate) J1443 are Non-preferred products. The preferred products are: Infed (iron dextran) J1750, Venofer (iron sucrose) J1756, Ferrlecit (sodium ferric gluconate cmplx) J2916

Prior Authorization Request

Medicare Part B 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** (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

☐ 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 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 – Iron Salt Drugs PA

Drug Name(s):

FERAHEME	**FERUMOXYTOL**
INJECTAFER	**FERRIC CARBOXYMALTOSE**
TRIFERIC	**FERRIC PYROPHOSPHATE**
MONOFERRIC	**DERISOMALTOSE**
INFED	**IRON DEXTRAM**
VENOFER	**IRON SUCROSE**

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.

Exclusion Criteria:

N/A

Prescriber Restrictions:

N/A

Coverage Duration:

Approvals will be for 12 months

FDA Indications:

Feraheme, Injectafer, Venofer, InFed, Monoferric

- Chronic kidney disease - Iron deficiency anemia (Injectafer: only for nondialysis dependent)
- Iron deficiency anemia, Intolerant or unsatisfactory response to oral iron

Triferic

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

Off-Label Uses:

Injectafer

- 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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