|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | | **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

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| --- |
| **CLINICAL INFORMATION** |
| **STEP THERAPY**  **Iron Deficiency Anemia**  Preferred:  Oral Iron Supplements **(No PA Required)** THEN  Injectable Iron Supplements:  INFed  Venofer  Ferrlecit **(No PA Required)**  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.

**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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