Updated: 03/2019
PARP Approved: 03/2019

Gateway Health
Prior Authorization Criteria
IV/Injectable Iron Medications

All requests for IV/Injectable Iron Medications require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

IV/Injectable Iron Medications Prior Authorization Criteria:

IV/Injectable Iron Medications addressed in this policy include: Injectafer (ferric carboxymaltose injection), Feraheme (ferumoxytol injection)

For all requests for IV/Injectable Iron Medications all of the following criteria must be met:

- The member must be 18 years of age or older
- The member has a documented trial and failure or an intolerance or contraindication to low molecular weight iron dextran (Infed).
- The member has a documented trial and failure or intolerance of oral iron therapy or oral therapy would be inappropriate due to one of the following reasons:
    - TSAT < 12%
    - Hemoglobin (Hgb) < 7 g/dL
    - Severe or ongoing blood loss
    - Co-existing condition that would prevent absorption of oral iron therapy

Coverage may be provided with a diagnosis of iron deficiency anemia without chronic kidney disease and the following criteria is met:

- Member has laboratory documentation supporting one of the following:
    - Measured ferritin level is less than 15 mcg/L
    - Measured serum iron level and transferrin saturation level are below the laboratory's lower range of normal; **AND** measured total iron-binding capacity is above the laboratory's upper range of normal
- **Initial Duration of Approval:** 3 months
- **Reauthorization criteria**
    - Documentation showing a normalized hemoglobin (13.5 to 17.5 g per deciliter for men, 12.0 to 15.5 grams per deciliter for women)
        - If the member fails to reach normalized hemoglobin levels, a statement of medical necessity from the provider is required
    - Documentation of a co-existing condition that would prevent absorption of oral iron therapy, failure to transition patient to oral therapy, or provider justification for not attempting an additional trial of oral therapy.
- **Reauthorization Duration of approval:** 3 months for a total duration of 6 months
    - If the request is for a duration of therapy greater than 6 months, a statement of medical necessity from the provider is required

Coverage may be provided with a diagnosis of iron deficiency anemia with chronic kidney disease and the following criteria is met:

- Ferritin ≤ 500 ng/ml (≤ 500 mcg/L)
- Transferrin saturation (TSAT) ≤ 30%
    - This requirement does not apply to patients on hemodialysis concurrently treated with an erythropoiesis stimulating agent
- For Injectafer only: member must be non-dialysis-dependent
- **Initial Duration of Approval:** 3 months
- **Reauthorization criteria**
    - Documentation of improved Hemoglobin (Hgb) from baseline **AND** Transferrin saturation (TSAT) ≤ 30% **AND** Ferritin ≤ 500 ng/ml (≤ 500 mcg/L)
    - Documentation of a co-existing condition that would prevent absorption of oral iron therapy, failure to transition patient to oral therapy, or provider justification for not attempting an additional trial of oral therapy.
    - For Injectafer only: member must still be non-dialysis-dependent

Reauthorization Duration of approval: 12 months

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

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IV IRON MEDICATION PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Gateway Health℠ Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:
Gateway ID:	Member weight: _____pounds or _____kg

REQUESTED DRUG INFORMATION

Medication:	Strength:
Frequency:	Duration:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:

Billing Information

This medication will be billed: ☐ at a pharmacy **OR**
☐ medically (if medically please provide a JCODE:_____

Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

Diagnosis: _____

Please check all applicable boxes:

☐ Patient has severe or ongoing blood loss
☐ Patient has chronic kidney disease, is on hemodialysis, and is being treated with erythropoiesis stimulating agents
☐ Patient has chronic kidney disease and is non-dialysis-dependent

Does the patient have a co-existing condition that would prevent absorption of oral iron therapy? ☐ Yes ☐ No
If Yes, please specify: _____
_____
_____

LABORATORY VALUES

Lab	Initial (Pre-Treatment) Level	Reference Range	Date	Post-Therapy Level (Reauthorization only)	Reference Range	Date
Transferrin saturation (TSAT)						
Hemoglobin (Hgb)						
Serum Iron						
Ferritin						
Total Iron-Binding Capacity						

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MEMBER INFORMATION

Member Name:	DOB:
Gateway ID:	Member weight: _____pounds or _____kg

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

REAUTHORIZATION

Is the member currently pregnant or breastfeeding? ☐ Yes ☐ No

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date