Mass General Brigham
Health Plan

Iron Agents and Chelators
Effective 06/30/2023

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	N/A		

Overview

No PA	Drugs that require PA
IV Iron Agents	
Ferrlecit® # (sodium ferric gluconate complex)	Feraheme® (ferumoxytol)*
Infed® (low molecular weight iron dextran)	Injectafer® (ferric carboxymaltose injection) [MB]
Triferic® (ferric pyrophosphate citrate) [MB]	Monoferric® (ferric derisomaltose)
Venofer® (iron sucrose)	
Oral Iron Agents	
ferrous fumarate	Accrufer® (ferric maltol)
ferrous gluconate	Auryxia® (ferric citrate)
ferrous sulfate	
Iron Chelators	
Desferal® # (deferoxamine)	Ferriprox® (deferiprone)*
Exjade® # (deferasirox 125 mg, 250 mg, 500 mg)	
Jadenu® # (deferasirox 90 mg, 180 mg, 360 mg)	

This is a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
* Available as an A-rated generic. Both brand and A-rated generic require PA.
MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. The plan does not pay for this drug to be dispensed through the retail pharmacy.

FDA Approved Indications for IV Iron Agents:

IV Iron Agents	FDA Approved Indications

Feraheme® (ferumoxytol)	Treatment of iron deficiency anemia in adult patients who have intolerance to or unsatisfactory response to oral iron or who have CKD Treatment of patients with documented iron deficiency in whom oral administration is unsatisfactory or impossible
Ferrlecit® (sodium ferric gluconate complex)	Treatment of iron deficiency anemia in adult patients and in pediatric patients six years of age or older with chronic kidney disease receiving hemodialyses who are receiving supplemental epoetin therapy
INFeD® **(low molecular weight iron dextran)**	Treatment of patients with documented iron deficiency in whom oral administration is unsatisfactory or impossible
Monoferric® (ferric derisomaltose)	Treatment of iron deficiency anemia in adult patients who have intolerance to oral iron or have had unsatisfactory response to oral iron, or who have non-hemodialysis dependent chronic kidney disease
Injectafer® (ferric carboxymaltose injection)	Treatment of iron deficiency anemia in adult patients who have intolerance or have had an unsatisfactory response to oral iron or who have non-dialysis-dependent chronic kidney disease Treatment of patients with documented iron deficiency in whom oral administration is unsatisfactory or impossible
Venofer® **(iron sucrose)**	Treatment of iron deficiency anemia in patients with CKD

Coverage Guidelines

Authorization may be reviewed on a case by case basis for members who are new to the plan currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted for members when all the following criteria are met, and documentation is provided:

Accrufer® (ferric maltol)
Auryxia® (ferric citrate)
ALL of the following:

1. Diagnosis of **ONE** of the following:
    a. For Accrufer, iron deficiency
    b. For Auryxia, iron deficiency anemia
2. Physician attestation of inadequate response or adverse reaction to **TWO** of the following oral iron products:
    a. Ferrous fumarate
    b. Ferrous gluconate

c. Ferrous sulfate
d. Polysaccharide iron complex

3. Member has attempted strategies to improve tolerability of other iron products if gastrointestinal adverse events occurred. Examples include:
    a. Increasing the dosing interval to every other day
    b. Making dietary modifications, such as taking iron with food or milk
    c. Switching to a formulation with lower elemental iron
    d. Switching from a tablet to a liquid for easier titration
    e. Use of a stool softener or bulk-forming laxative

Auryxia® (ferric citrate)

1. Diagnosis of hyperphosphatemia in chronic kidney disease on dialysis

Feraheme® (ferumoxytol)
Injectafer® (ferric carboxymaltose injection)
Monoferric® (ferric derisomaltose)
ALL of the following:

1. Diagnosis of iron deficiency anemia
2. Physician attestation of inadequate response or adverse reaction to **ONE** or contraindication to all of the following:
    a. INFeD® (low molecular weight iron dextran)
    b. sodium ferric gluconate complex
    c. Venofer® (iron sucrose)
3. If request is for Brand Name Feraheme®, the member must meet the above criteria and provide medical records documenting an inadequate response or adverse reaction to the generic ferumoxytol *(refer to non-FDA approved and non-rebate medications guidelines)*

Notes:
If any of the following contraindications to treatment with INFeD® (low molecular weight iron dextran) are documented by the prescriber, a trial with INFeD® (low molecular weight iron dextran) may be bypassed; however, trial with sodium ferric gluconate complex or Venofer® (iron sucrose) may still be appropriate:

a. Pregnancy
b. Asthma
c. Hepatic impairment
d. Acute kidney infection
e. Rheumatoid arthritis
f. Hypersensitivity to any component of the formulation

Ferripox® (deferiprone)
ALL of the following:

1. Diagnosis of **ONE** of the following:
    a. transfusional iron overload due to thalassemia syndromes
    b. transfusional iron overload due to sickle cell disease or other anemia
2. Member is under the care of an appropriate specialist (hematologist, oncologist)
3. For the tablet formulation, the member is ≥8 years of age
4. For the oral solution formulation **ONE** of the following:
    a. member is ≥ 3 to < 13 years of age
    b. medical necessity for the use of an oral solution formulation (e.g., inability to swallow oral tablets)

5. Physician attestation of inadequate response or adverse reaction to **ONE** or contraindication to **BOTH** of the following:
    a. deferoxamine
    b. deferasirox
6. If request is for Brand Name Ferriprox®, the member must meet the above criteria and provide medical records documenting an inadequate response or adverse reaction to generic deferiprone *(refer to non-FDA approved and non-rebate medications guidelines)*

Continuation of Therapy

Resubmission by prescriber will infer a positive response to therapy

Limitations

1. Initial approvals will be granted for the following durations:
    a. **IV Iron Agents:** 1 month or treatment course up to 6 months
    b. **Iron Chelators:** 6 months
    c. **Accrufer® and Auryxia®:** 6 months
2. Reauthorizations will be granted for the following durations:
    a. **IV Iron Agents:** 1 month or treatment course up to 12 months
    b. **Accrufer®, Auryxia®, and Iron Chelators:** 12 months

References

1. Feraheme® [package insert]. Lexington (MA): AMAG Pharmaceuticals, Inc; 2022 Jun.
2. Ferrlecit® [package insert]. Bridgewater (NJ): Sanofi-Aventis U.S. LLC; 2022 Mar.
3. INFeD® [package insert]. Madison (NJ): Allergan USA, Inc; 2021 Apr.
4. Injectafer® [package insert]. Shirley (NY): American Regent, Inc; 2022 Feb.
5. Monoferric® [prescribing information]. Morristown (NJ): Pharmacosmos Therapeutics Inc.; 2022 Aug.
6. Venofer® [package insert]. Shirley (NY): American Regent, Inc; 2020 Oct.
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20. Exjade® [package insert]. East Hanover (NJ): Novartis; 2020 Jul.
21. Jadenu® [package insert]. East Hanover (NJ): Novartis; 2020 Jul.
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Review History

02/01/2022 - Reviewed and created for P&T. Matched MH UPPL criteria to be in compliance with Masshealth unified formulary requirements. Effective 4/1/23.

06/14/23 – Reviewed and updated for P&T. Admin update: Injectafer is only available through MB. Effective 6/30/23.