Effective Date: 08/01/2018
Last P&T Approval/Version: 0727/2022
Next Review Due By: 07/2023
Policy Number: C14569-A

Iron Deficiency Anemia Agents

PRODUCTS AFFECTED

Feraheme (ferumoxytol), Injectafer (ferric carboxymaltose), Monoferric (ferric derisomaltose)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.
This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Treatment of iron deficiency anemia in patients who have intolerance or an unsatisfactory response to oral iron, Treatment of iron deficiency anemia in patients with chronic kidney disease (CKD), Treatment of iron deficiency anemia in patients who have non-dialysis dependent CKD

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review.

A. FOR ALL INDICATIONS:
1. Documentation of member having iron deficiency anemia evidenced by a laboratory report within the last 14 days of a Hgb level of <12 g/dL AND Ferritin ≤100 ng/mL OR Ferritin ≤300 ng/mL when transferrin saturation (TSAT) ≤30%; [DOCUMENTATION REQUIRED]
AND

2. The member has: experienced inadequate response to a consistent trial of oral iron or has a documented intolerance or contraindication to oral iron therapy OR has been diagnosed with a condition in which oral iron is not appropriate which includes ANY of the following: (i) member is unable to tolerate gastrointestinal side effects of oral iron, (ii) member has a malabsorption syndrome, (iii) member has had gastric surgery that impairs the intestinal absorption of oral iron, (iv)member has severe or ongoing blood loss, (v) member is in second trimester of pregnancy with hemoglobin <10.5g, (vi) member is in third trimester of pregnancy or (v) member is being treated for an oncology indication
   AND
3. (a) The member has a documented failure or intolerance to Infed, Venofer, or Ferrlecit.
   OR
   (b) IF BEING USED FOR CANCER OR CHEMO-RELATED ANEMIA: Prescriber attestation of medical necessity for requested iron preparation.
   AND
4. FOR INJECTAFER OR MONOFERRIC: Documentation of member's current weight (within the last 30 days)

CONTINUATION OF THERAPY:

A. FOR ALL INDICATIONS:

1. Documentation of labs, chart notes documenting additional need due to continued low hemoglobin levels [DOCUMENTATION REQUIRED]
   AND
2. FOR INJECTAFER OR MONOFERRIC: Documentation of member's current weight (within the last 30 days)

DURATION OF APPROVAL:

Initial authorization: 1 month, Continuation of Therapy: 3 months

PRESCRIBER REQUIREMENTS:

No requirements

AGE RESTRICTIONS:

No restrictions

QUANTITY:

Feraheme (ferumoxytol) 1020 mg per 28 days
Injectafer (ferric carboxymaltose): For patients weighing 50 kg or more: 1500 mg per 28 days (2 dose course), OR 15 mg/kg (max 1000 mg) for single dose treatment course; <50 kg: 15 mg/kg body weight
Monoferric (ferric derisomaltose): For patients weighing 50 kg or more: 1000 mg; <50 kg: 20 mg/kg actual body weight per 28 days

Maximum Quantity Limits – << based on FDA label>>

PLACE OF ADMINISTRATION:

The recommendation is that infused medications in this policy will be for pharmacy or medical benefit coverage administered in a place of service that is a non-inpatient hospital facility-based location.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:

Intravenous Infusion

DRUG CLASS:

Iron Salts

FDA-APPROVED USES:
Feraheme (ferumoxytol): indicated for the treatment of iron deficiency anemia (IDA) in adult patients who have intolerance to oral iron or have had unsatisfactory response to oral iron or who have chronic kidney disease (CKD)

Injectafer (ferric carboxymaltose), Monoferric (ferric derisomaltose): indicated for the treatment of iron deficiency anemia (IDA) in adult patients who have intolerance to oral iron or have had unsatisfactory response to oral iron, or who have non-dialysis dependent chronic kidney disease.

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Iron deficiency anemia occurs when the body's red blood cell production is reduced due to low iron stores. Worldwide, iron deficiency anemia is the most common nutritional disorder. It is estimated that one-half of anemia cases are due to iron deficiencies. Iron deficiency anemia is most commonly seen in patients with certain types of cancer, chronic kidney disease (CKD), premenopausal women with abnormal bleeding, pregnancy, inflammatory bowel disease, and some gastrointestinal disorders.5 Iron deficiency anemia also occur in other chronic conditions or due to surgery. In most instances, oral iron replacement therapy should be attempted prior to parenteral iron administration. Some conditions, namely cancer, CKD, inflammatory bowel disease and others may be inappropriate to use oral iron replacement therapy.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Feraheme (ferumoxytol), and Injectafer (ferric carboxymaltose) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Feraheme (ferumoxytol) Monoferric (ferric derisomaltose), and Injectafer (ferric carboxymaltose) include hypersensitivity to the product, including inactive components. Feraheme is also contraindicated in patients with a history of allergic reaction to any intravenous iron product

OTHER SPECIAL CONSIDERATIONS:
Boxed warning: Feraheme: risk for serious hypersensitivity/anaphylaxis reactions

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
Q0138	Injection, ferumoxytol, for treatment of iron deficiency anemia, 1mg (non-esrd use)
Q0139	Injection, ferumoxytol, for treatment of iron deficiency anemia 1mg for esrd on dialysis)

J1439	Injection, ferric carboxymaltose, 1mg
J1437	Injection, ferric derisomaltose, 10 mg

AVAILABLE DOSAGE FORMS:
Feraheme 510 mg/17mL
Injectafer 750 mg/15mL
Injectafer 1000 mg/20 mL
Monoferric 1000 mg/10 mL
Monoferric 500 mg/5 mL
Monoferric 100 mg/mL

REFERENCES

1. Feraheme (ferumoxytol) [package insert]. Waltham, MA. AMAG Pharmaceuticals. June 2022.
2. Injectafer (ferric carboxymaltose) [package insert]. Shirley, NY. AmericanRegent,Inc. February 2022
3. Monoferric (ferricderisomaltose) [package insert]. Morristown, NJ. Pharmacosmos Therapeutics Inc. ~~July 2020.~~February 2022
4. World Health Organization. Iron Deficiency Anemia: Assessment, Prevention, and Control: AGuide for Program Managers. Geneva, Switzerland: World Health Organization; 2001.
5. Johnson-Wimbley TD, Graham DY. Diagnosis and management of iron deficiency anemia in the 21st century. Therap Adv Gastroenterol. 2011;4(3):177–184.
6. Short WS, Domagalski JE. Iron Deficiency Anemia: Evaluation and Management. AmFamPhysician. 2013 Jan 15;87(2):98-104.
7. National Comprehensive Cancer Network. 2022. Hematopoietic Growth Factors (Version 1.2022). [online] Available at: < growthfactors.pdf (nccn.org)> [Accessed 30 June 2022]

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Quantity References	Q3 2022
Q2 2022 Established tracking in new format	Historical changes on file