Clinical Policy: Ferric Derisomaltose (Monoferric)

Reference Number: LA.PHAR.480
Effective Date:
Last Review Date: 05.01.23
Line of Business: Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Please note: This policy is for medical benefit

Description
Ferric derisomaltose (Monoferric™) injection is an iron replacement product.

FDA Approved Indication(s)
Monoferric is indicated for treatment of iron deficiency anemia (IDA) in adult patients:
- Who have intolerance to oral iron or have had unsatisfactory response to oral iron
- Who have non-hemodialysis dependent chronic kidney disease (NDD-CKD).

Policy/Criteria
Provider must submit documentation (including such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of Louisiana Healthcare Connections® that Monoferric is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Iron Deficiency Anemia with Chronic Kidney Disease (must meet all):
1. Diagnosis of IDA and CKD;
2. IDA is confirmed by either of the following:
   a. Transferrin saturation (TSAT) ≤ 30%;
   b. Serum ferritin ≤ 500 ng/mL;
3. If CKD does not require hemodialysis or peritoneal dialysis, oral iron therapy is not optimal due to any of the following:
   a. TSAT < 12%;
   b. Hgb < 7 g/dL;
   c. Symptomatic anemia;
   d. Severe or ongoing blood loss;
   e. Oral iron intolerance;
   f. Unable to achieve therapeutic targets with oral iron;
   g. Co-existing condition that may be refractory to oral iron therapy;
4. Dose does not exceed 1000 mg elemental iron (10 mL) per infusion/injection.

Approval duration: 3 months

B. Iron Deficiency Anemia without Chronic Kidney Disease (must meet all):
1. Diagnosis of IDA confirmed by any of the following:

a. Serum ferritin < 15 ng/mL or < 30 ng/mL if pregnant;
b. Serum ferritin ≤ 41 ng/mL and Hgb < 12 g/dL (women)/< 13 g/dL (men);
c. TSAT < 20%;
d. Absence of stainable iron in bone marrow;
e. Increased soluble transferring receptor (sTfR) or sTfR-ferritin index;
f. Increased erythrocyte protoporphyrin level;

2. Oral iron therapy is not optimal due to any of the following:
   a. TSAT < 12%;
   b. Hgb < 7 g/dL;
   c. Symptomatic anemia;
   d. Severe or ongoing blood loss;
   e. Oral iron intolerance;
   f. Unable to achieve therapeutic targets with oral iron;
   g. Co-existing condition that may be refractory to oral iron therapy;
3. At the time of the request, member does not have CKD;
4. Dose does not exceed 1000 mg elemental iron (10 mL) per infusion/injection.

Approval duration: 3 months

C. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: LA.PMN.53 for Medicaid.

II. Continued Approval Criteria

A. Iron Deficiency Anemia with Chronic Kidney Disease (must meet all):

1. Currently receiving medication via Louisiana Healthcare Connections benefit or member has previously met initial approval criteria;
2. Documentation of one of the following laboratory results measured since the last IV iron administration:
   a. TSAT ≤ 30%;
   b. Serum ferritin ≤ 500 ng/mL;
3. If request is for a dose increase, new dose not exceed 1000 mg elemental iron (10 mL) per infusion/injection.

Approval duration: 3 months

B. Iron Deficiency Anemia without Chronic Kidney Disease (must meet all):

1. Currently receiving medication via Louisiana Healthcare Connections benefit or member has previously met initial approval criteria;
2. Documentation of one of the following laboratory results measured since the last IV iron administration:

a. Serum ferritin < 15 ng/mL or < 30 ng/mL if pregnant;
b. Serum ferritin ≤ 41 ng/mL and Hb < 12 g/dL (women)/< 13 g/dL (men);
c. TSAT < 20%;
d. Absence of stainable iron in bone marrow;
e. Increased sTfR or sTfR-ferritin index;
f. Increased erythrocyte protoporphyrin level;

3. At the time of the request, member does not have CKD;
4. If request is for a dose increase, new dose does not exceed 1000 mg elemental iron (10 mL) per infusion/injection.

Approval duration: 3 months

C. Other diagnoses/indications (must meet 1 or 2):

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: LA.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – LA.PMN.53 for Medicaid, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

CKD: chronic kidney disease
Hgb: hemoglobin
IDA: iron deficiency anemia
NDD-CKD: non-hemodialysis-dependent chronic kidney disease
TSAT: transferrin saturation
sTfR: soluble transferring receptor

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Examples of OTC Oral Iron Formulations*		
Ferrous fumarate (Ferretts, Ferrimin 150, Hemocyte)	Varies	
Ferrous gluconate (Ferate)		

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Ferrous sulfate (BProtected Pedia Iron, Fer-In-Sol, FeroSul, FerrouSul, Iron Supplement, Iron Supplement Childrens, Slow Fe, Slow Iron)		
Polysaccharide-iron complex (EZFE 200, Ferrex 150, Ferrix x-150, Myferon 150, NovaFerrum 125, NovaFerrum 50, NovaFerrum Pediatric Drops, Nu-Iron, Poly-Iron 150)		

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.
**Oral formulations include elixirs, liquids, solutions, syrups, capsules, and tablets - including delayed/extended-release tablets.*

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): Serious hypersensitivity to Monoferric or any of its components.
- Boxed warning(s): None reported.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
IDA	≥ 50 kg: 1,000 mg IV as a single dose. Repeat dose if IDA reoccurs. < 50 kg: 20 mg/kg actual body weight by IV infusion as a single dose. Repeat dose if IDA reoccurs.	1,000 mg per dose (treatment may be repeated)

VI. Product Availability

Single-dose vials: 1,000 mg/10 mL, 500 mg/5 mL, 100 mg/mL

VII. References

1. Monoferric Prescribing Information. Holbaek, Denmark: Pharmacosmos; February 2022. Available at https://monoferric.com/. Accessed February 23, 2021.
2. KDIGO 2012 clinical practice guideline for evaluation and management of chronic kidney disease. *Kidney International Supplements.* January 2013; 3(1): 1-136.
3. KDIGO 2012 clinical practice guideline for anemia in chronic kidney disease. *Kidney International Supplements.* August 2012; 2(4): 279-331.
4. Camaschella C. Iron-Deficiency Anemia. *N Engl J Med.* 2015; 372: 1832-43. DOI: 10.1056/NEJMra1401038.
5. Short MW, Domagalski JE. Iron Deficiency Anemia: Evaluation and Management. *Am Fam Physician.* 2013; 87(2): 98-104. http://www.aafp.org/afp/2013/0115/p98.pdf.
6. Ko CW, Siddique SM, Patel A, et al. AGA clinical practice guidelines on the gastrointestinal evaluation of iron deficiency anemia. Gastroenterology 2020;159:1085-94.
7. DRUGDEX® System [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed February 23, 2021.

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J1437	Injection, ferric derisomaltose, 10 mg

Reviews, Revisions, and Approvals	Date	LDH Approval Date
Policy created	05.01.23	

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. LHCC retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care and are solely responsible

for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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