Clinical Policy: Ferric Derisomaltose (Monoferric)

Reference Number: CP.PHAR.480
Effective Date: 06.01.20
Last Review Date: 05.24
Line of Business: Commercial, HIM, Medicaid

Coding Implications
Revision Log

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

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 health plans affiliated with Centene Corporation® 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. Member meets both of the following (a and b):
   a. Failure of both of the following, unless clinically significant adverse effects are experienced or both are contraindicated: **Ferrlecit®** and **Venofer®**;
   b. If member has satisfied criteria 4a above, failure of **generic Feraheme®**, unless contraindicated or clinically significant adverse effects are experienced;
5. 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. Member meets both of the following (a and b):
   a. Failure of two of the following, unless clinically significant adverse effects are experienced or all are contraindicated: **Ferrlecit**, **Infed**®, or **Venofer**;
   b. If member has satisfied criteria 4a above, failure of **generic Feraheme**, unless contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed 1000 mg elemental iron (10 mL) per infusion/injection.

Approval duration: 3 months

C. Management of Cancer- and Chemotherapy-Induced Anemia (off-label) (must meet all):
1. Diagnosis of iron deficiency, with one of the following iron statuses (a, b, or c):
   a. Absolute iron deficiency confirmed by both (i and ii):
      i. Serum ferritin < 30 ng/mL;
      ii. TSAT < 20%;
   b. Possible functional iron deficiency confirmed by both (i and ii):
      i. Serum ferritin 500-800 ng/mL;
      ii. TSAT < 50%;
   c. Functional iron deficiency with (i, ii, and iii):
      i. Serum ferritin 30-500 ng/mL;
      ii. TSAT < 50%;
      iii. An erythropoietin-stimulating agent (e.g., Epogen®, Procrit®, Aranesp®, Retacrit®) prescribed in combination;
2. Prescribed by or in consultation with an oncologist;
3. Member is prescribed chemotherapy for cancer;
4. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).*

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

D. 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 one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
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: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
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. Member meets both of the following (a and b):
   a. Failure of both of the following, unless clinically significant adverse effects are experienced or both are contraindicated: **Ferrlecit** and **Venofer**;
   b. If member has satisfied criteria 3a above, failure of **generic Feraheme**, unless contraindicated or clinically significant adverse effects are experienced;
4. 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. Member meets one of the following (a or b):

a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*

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. Member meets both of the following (a and b):
   a. Failure of two of the following, unless clinically significant adverse effects are experienced or all are contraindicated: **Ferrlecit**, **Infed**, or **Venofer**;
   b. If member has satisfied criteria 4a above, failure of **generic Feraheme**, unless contraindicated or clinically significant adverse effects are experienced;
5. 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. Management of Cancer- and Chemotherapy-Induced Anemia (off-label) (must meet all)**:**

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Monoferric for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).*
   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

D. 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 one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business:

CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or

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: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.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 – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.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)	Varies	
Ferrous gluconate (Ferate)		
Ferrous sulfate (BProtected Pedia Iron, Fer-In-Sol, FeroSul, Iron Supplement, Iron Supplement Childrens, Slow Fe, Slow Iron)		
Polysaccharide-iron complex (EZFE 200, Ferrex 150, Ferrix x-150, IFerex 150, NovaFerrum 125, NovaFerrum, NovaFerrum Pediatric Drops, Nu-Iron, Poly-Iron 150)		
Injectable iron agents		
Sodium ferric gluconate (Ferrlecit)	Varies	
Infed (iron dextran)		
Venofer (iron sucrose)		
Ferumoxytol (Feraheme)		

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. Morristown, NJ: Pharmacosmos; January 2024. Available at https://www.monoferric.com/. Accessed January 11, 2024.
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. Babitt JL, Eisenga MF, Haase VH, et al. Controversies in optimal anemia management: conclusions from a Kidney Disease: Improving Global Outcomes (KDIGO) Conference. Kidney Int. 2021;99(6):1280-1295.
5. Camaschella C. Iron deficiency. Blood. 2019 Jan 3;133(1):30-39.
6. 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.
7. DRUGDEX® System [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed February 11, 2024.

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	P&T Approval Date
Policy created	01.24.20	05.20
2Q 2021 annual review: no significant changes; updated max dosing per PI; references reviewed and updated.	02.23.21	05.21
2Q 2022 annual review: no significant changes; references reviewed and updated.	02.25.22	05.22
Template changes applied to other diagnoses/indications and continued therapy section.	10.03.22	
2Q 2023 annual review: Per February SDC, updated initial criteria to require failure of the following: for IDA and CKD Ferrlecit and Venofer; for IDA without CKD two of Ferrlecit, Infed, or Venofer; additionally, added redirection to Feraheme in a step-wise fashion if member has intolerance or contraindication to all preferred injectable agents; references reviewed and updated.	02.21.23	05.23
Per health plan request and SDC, added redirections from initial approval criteria to continued therapy.	08.15.23	
Per health plan request and SDC, revised to template redirection language; revised redirection to Feraheme to instead require generic Feraheme.	11.08.23	
2Q 2024 annual review: added criteria for NCCN-supported indication of cancer- and chemotherapy-induced anemia; references reviewed and updated.	01.11.24	05.24

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. The Health Plan 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. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

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 Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. 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. The Health Plan 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.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.