Drug Policy:

Iron Products

POLICY NUMBER UM ONC_1181	SUBJECT Iron Products [Infed (iron dextran), Venofer (iron sucrose), Ferrlecit (ferric gluconate), Feraheme (ferumoxytol), Monoferric (ferric derisomaltose), Feraheme (ferumoxytol), Injectafer (ferric carboxymaltose), Accrufer (ferric maltol)]	DEPT/PROGRAM UM Dept	PAGE 1 of 4
DATES COMMITTEE REVIEWED 09/20/11, 05/09/12, 08/01/12, 05/17/13, 07/10/13, 07/24/14, 12/16/15, 12/20/16, 12/14/17, 11/10/18. Reinstated 10/28/20, 11/11/20, 12/09/20, 02/10/21, 04/14/21, 10/13/21, 11/15/21, 05/11/22, 09/14/22, 03/08/23	APPROVAL DATE March 8, 2023	EFFECTIVE DATE March 31, 2023	COMMITTEE APPROVAL DATES 09/20/11, 05/09/12, 08/01/12, 05/17/13, 07/10/13, 07/24/14, 12/16/15, 12/20/16, 12/14/17, 11/10/18. Reinstated 10/28/20, 11/11/20, 12/09/20, 02/10/21, 04/14/21, 10/13/21, 11/15/21, 05/11/22, 09/14/22, 03/08/23
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee	
URAC STANDARDS HUM v8: UM 1-2; UM 2-1	NCQA STANDARDS UM 2	ADDITIONAL AREAS OF IMPACT	
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS	APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid	

I. PURPOSE

To define and describe the accepted indications for Iron Products [Infed (iron dextran), Venofer (iron sucrose), Ferrlecit (ferric gluconate), Feraheme (ferumoxytol), Monoferric (ferric derisomaltose), Feraheme (ferumoxytol), Injectafer (ferric carboxymaltose), Accrufer (ferric maltol)] usage in the treatment of cancer, including FDA approved indications, and off-label indications.

New Century Health (NCH) is responsible for processing all medication requests from network ordering providers. Medications not authorized by NCH may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

A. Continuation requests for a not-approvable medication shall be exempt from this NCH policy provided:

1. The requested medication was used within the last year, AND
2. The member has not experienced disease progression and/or no intolerance to the requested medication, AND
3. Additional medication(s) are not being added to the continuation request.

B. Iron Deficiency

1. The member has iron deficiency with or without anemia with the presence of any ONE or MORE of the following:
   a. Serum ferritin less than 30 ng/mL
   b. Transferrin saturation (TSAT) less than 20%
   c. Absence of stainable iron in the bone marrow
   d. Improvement of anemia with iron replacement therapy (oral or parenteral)

   OR
2. The member is receiving (or has received within the last 8 weeks) myelosuppressive chemotherapy AND has chemotherapy induced anemia defined as a Hgb less than 10 g/dL or HCT less than 30 (levels obtained within the last 4 weeks) AND iron products may be used with or without concomitant ESA therapy. Acceptable labs in this situation include a Ferritin less than 30 ng/mL and/or a TSAT (transferrin saturation) of less than 20% within the last 12 months.

   OR
3. The member has anemia of chronic kidney disease defined by a GFR of less than 60 mL/min AND a Hgb of less than 10 gm/dL or HCT less than 30 (levels obtained within the last 4 weeks). Parenteral iron products may be used with or without concomitant ESA therapy. Acceptable labs in this situation include a Ferritin of less than 30 ng/mL and/or a TSAT (transferrin saturation) of less than 20%.
4. NOTE: Per NCH policy, the following products are not approvable for the treatment of iron deficiency. The above Policy Position is based on a lack of level 1 evidence (randomized trials and/or meta-analyses) supporting superior outcomes for any Not Approvable iron replacement products over the Approvable products. The use of a Not Approvable product is supported, per NCH policy, if the member has a history of hypersensitivity reaction or other adverse effects from the Approvable product(s):
   a. Accrufer (ferric maltol) is a not approvable oral iron product. The Approvable oral ferrous iron products are, but not limited to, ferrous sulfate, ferrous gluconate, and/or ferrous fumarate.
   b. Monoferric (ferric derisomaltose) and Injectafer (ferric carboxymaltose) are not approvable parenteral iron products. The Approvable parenteral iron products are Infed (iron dextran), Venofer (iron sucrose), Ferrlecit (ferric gluconate), and/or Feraheme (ferumoxytol).

III. EXCLUSION CRITERIA

A. Dosing exceeds single dose limit of Accrufer (ferric maltol) 30 mg and treatment exceeds the maximum limit of 60 (30 mg) capsules/month.

B. Dosing exceeds single dose limit of Infed (iron dextran) 100 mg or total replacement dose of 1,000 mg per course of treatment.

C. Dosing exceeds single dose limit of Ferrlecit (sodium ferric gluconate) 125 mg or total replacement dose of 1,000 mg per course of treatment.

D. Dosing exceeds single dose limit of Venofer (iron sucrose) 300 mg per dose or total replacement dose of 1,000 mg per course of treatment.

E. Dosing exceeds single dose limit of Injectafer (ferric carboxymaltose) 750 mg or total replacement dose of 1,500 mg per course of treatment.

F. Dosing exceeds single dose limit of Feraheme (ferumoxytol) 510 mg or total replacement dose of 1020 mg per course of treatment.

G. Dosing exceeds single dose limit and total replacement dose of Monoferric (ferric derisomaltose) 1,000 mg.

H. Investigational use of Iron Products with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:

I. Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.

J. Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.

K. Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definitions of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of less than 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.

L. Whether the experimental design, considering the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).

M. That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.

N. That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.

O. That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

IV. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

V. ATTACHMENTS

A. None

VI. REFERENCES

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B. Monoferric prescribing information. Pharmacosmos Therapeutics Inc. Morristown, NJ 2022.

C. Injectafer prescribing information. American Regent, Inc. Shirley, NY 2021.

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F. Venofer prescribing information. American Regent, Inc. Shirley, NY 2022.

G. Feraheme prescribing information. AMAG Pharmaceuticals Inc. Lexington, MA 2022.

H. Clinical Pharmacology Elsevier Gold Standard 2023.

I. Micromedex® Healthcare Series: Micromedex Drugdex Ann Arbor, Michigan 2023.

J. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2023.

K. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2023.

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R. NCQA UM 2023 Standards and Elements.