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	**APPROVAL DATE** November 15, 2021	**EFFECTIVE DATE** November 29, 2021	**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
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee	
URAC STANDARDS HUM 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. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

1. When health plan Medicaid coverage provisions—including any applicable PDLs (Preferred Drug Lists)—conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the Preferred Drug Guidelines OR
2. When health plan Exchange coverage provisions-including any applicable PDLs (Preferred Drug Lists)-conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the Preferred Drug Guidelines OR
3. For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, the Preferred Drug Guidelines shall follow NCH L1 Pathways when applicable, otherwise shall follow NCH drug policies AND
4. Continuation requests of previously approved, non-preferred medication are not subject to this provision AND
5. When applicable, generic alternatives are preferred over brand-name drugs.

B. Iron Deficiency

1. NOTE: Per NCH policy, the ferrous oral iron products (e.g., ferrous sulfate, ferrous gluconate, ferrous fumarate) are preferred over Accrufer (ferric maltol) and parenteral iron products for iron deficiency, unless the member has a history of hypersensitivity reaction or other adverse effects from the preferred oral products .The preferred parenteral iron products are Infed (iron dextran), Venofer (iron sucrose), Ferrlecit (ferric gluconate), and Feraheme (ferumoxytol) over Monoferric (ferric derisomaltose) or Injectafer (ferric carboxymaltose). This recommendation is based on a lack of level 1 evidence (randomized trials and/or meta-analyses) supporting superior outcomes for any of the non-preferred iron replacement products over the preferred products.
2. Iron products may be used as monotherapy in any of the following clinical condition:
   a. The member has iron deficiency with or without anemia with the presence of any ONE or MORE of the following:
      i. Serum ferritin < 30 ng/mL
      ii. Transferrin saturation (TSAT) < 20%
      iii. Absence of stainable iron in the bone marrow
      iv. Improvement of anemia with iron replacement therapy (oral or parenteral).

      OR
   b. The member is receiving (or has received within the last 8 weeks) myelosuppressive chemotherapy AND has chemotherapy induced anemia defined as a Hgb of < 8 gm/dL or HCT < 24 (as recommended by NCH L1 pathway) OR Hgb < 10 g/dL or HCT < 30 (as required by NCH policy) AND, iron products may be used with or without concomitant ESA therapy. Acceptable labs in this situation include a Ferritin of 30 ng/mL and/or a TSAT (transferrin saturation) of < 20%

      OR
   c. The member has anemia of chronic kidney disease defined by a GFR of < 60 mL/min AND a Hgb of < 12 gm/dL. Parenteral iron products may be used with or without concomitant ESA therapy. Acceptable labs in this situation include a Ferritin of < 30 ng/mL and/or a TSAT (transferrin saturation) of < 20%.

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 Ferrlecit (sodium ferric gluconate) 125 mg.

C. Dosing exceeds single dose limit of Venofer (iron sucrose) 300 mg per dose.

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

E. Dosing exceeds single dose limit of Feraheme (ferumoxytol) 510 mg or total replacement dose of 2.04 gms.

F. Dosing exceeds single dose limit of Monoferric (ferric derisomaltose) 1,000 mg,

G. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

IV. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

V. ATTACHMENTS

A. None

VI. REFERENCES

A. Accrufer prescribing information. Shield TX (UK) Ltd Wilmington DE 2021.

B. Monoferric prescribing information. Pharmacosmos Therapeutics Inc. Morristown, NJ 2020.

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

D. INFed prescribing information. Actavis Pharma, Inc. Parsippany, NJ 20210.

E. Ferrlecit prescribing information. Sanofi-Aventis U.S. LLC. Bridgewater, NJ 2020.

F. Venofer prescribing information. American Regent, Inc. Shirley, NY 2020.

G. Feraheme prescribing information. AMAG Pharmaceuticals Inc. Lexington, MA 2020.

H. Clinical Pharmacology Elsevier Gold Standard 2021.

I. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, CO 2021.

J. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2021.

K. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2021.

L. Kliger AS, et al. KDOQI US commentary on the 2012 KDIGO Clinical Practice Guideline for Anemia in CKD. Am J Kidney Dis. 2013 Nov;62(5):849-59.

M. Bohlius J, Bohlke K, Castelli R, Djulbegovic B, Lustberg MB, Martino M, Mountzios G, Peswani N, Porter L, Tanaka TN, Trifirò G, Yang H, Lazo-Langner A. Management of Cancer-Associated Anemia With Erythropoiesis-Stimulating Agents: ASCO/ASH Clinical Practice Guideline Update. J Clin Oncol. 2019 May 20;37(15):1336-1351. doi: 10.1200/JCO.18.02142. Epub 2019 Apr 10. PMID: 30969847.

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