Drug Policy:

Parenteral Iron Products

POLICY NUMBER UM ONC_1181	**SUBJECT** Parenteral Iron Products		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 3**
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	**APPROVAL DATE** November 11, 2020	**EFFECTIVE DATE** November 30, 2020	**COMMITTEE APPROVAL DATES** (latest version listed last) 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	
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 Parenteral Iron Products 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 available, generic alternatives are preferred over brand-name drugs.

B. Iron Deficiency

1. Note: Per NCH policy, the preferred parenteral iron products for iron deficiency are Infed (iron dextran), Venofer (iron sucrose), or Ferrlecit (ferric gluconate) over Feraheme (ferumoxytol) or Injectafer (ferric carboxymaltose) unless there are hypersensitivity reactions or intolerance to the preferred products.
2. Parenteral iron products may be used in any of the following clinical condition:
    a. The member has iron deficiency anemia defined as a Hgb of < 13 gm/dL for a male and < 12 gm/dL for a female with the presence of any ONE or MORE of the following:
        i. Serum ferritin < 30 ng/mL
        ii. Transferrin saturation < 20%
        iii. Absence of stainable iron in the bone marrow
        iv. Improvement of anemia with iron replacement therapy (oral or parenteral).
    b. The member has chemotherapy induced anemia defined as a Hgb of <10 gm/dL in a member who is receiving (or has received within the last 8 weeks) myelosuppressive chemotherapy. Parenteral iron is being used with or without concomitant ESA therapy. Acceptable labs in this situation include a Ferritin of < 800 ng/mL and a TSAT (transferrin saturation) of < 30%.
    c. The member has anemia of chronic kidney disease defined by a GFR of < 60 mL/min AND a Hgb of < 13 gm/dL for a male or < 12 gm/dL for a female. Parenteral iron is being used with or without concomitant ESA therapy.

III. EXCLUSION CRITERIA

A. Dosing exceeds single dose limit of Ferrlecit (sodium ferric gluconate) 125 mg.

B. Dosing exceeds single dose limit of Venofer (iron sucrose) 200 mg per dose.

C. Dosing exceeds single dose limit of Injectafer (ferric carboxymaltose) 750 mg or total replacement dose of 1500 mg.

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

E. 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. Injectafer prescribing information. American Regent, Inc. Shirley, NY. 2020.

B. INFed prescribing information. Actavis Pharma, Inc. Parsippany, NJ. 2015.

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

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

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

F. Clinical Pharmacology Elsevier Gold Standard. 2020.

G. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2020.

H. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2020.

New Century Health