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	**APPROVAL DATE** October 28, 2020	**EFFECTIVE DATE** October 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	
PRIMARY BUSINESS OWNER: UM **APPROVED BY:** Dr. Andrew Hertler		**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. Absolute iron deficiency
    a. The member has absolute iron deficiency, with or without anemia, and parenteral iron product is being used for ALL of the following clinical conditions:
        i. The member has documented failure or intolerance to Venofer (iron sucrose) or Ferrlecit (ferric gluconate) prior to use of Feraheme (ferumoxytol) or Injectafer (ferric carboxymaltose).
        ii. Serum ferritin < 30 ng/mL OR TSAT < 15 % (Labs obtained within the last 4 weeks).
2. Functional iron deficiency
    a. The member has functional iron deficiency, with or without anemia, and parenteral iron product is being used for ALL of the following clinical conditions:
        i. The member has documented failure or intolerance to Venofer (iron sucrose) or Ferrlecit (ferric gluconate) prior to use of Feraheme (ferumoxytol) or Injectafer (ferric carboxymaltose).
        ii. Serum ferritin < 100 ng/mL AND transferrin saturation < 20% (Labs obtained within the last 4 weeks).

III. EXCLUSION CRITERIA

A. Dosing exceeds single or total replacement dose limit of Infed (iron dextran) 1000 mg.

B. Dosing exceeds single dose limit of Ferrlecit (sodium ferric gluconate) 125 mg or total replacement dose of 1000 mg.

C. Dosing exceeds single dose limit of Venofer (iron sucrose) 300 mg or total replacement dose of 1000 mg.

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

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

F. 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.