MEDICATION COVERAGE POLICY

PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE

Health Plan of San Joaquin

POLICY:	ESA/Anemia of Chronic Disease	**P&T DATE:**	2/9/2021
CLASS:	Renal Disease/Genitourinary Disorders	**REVIEW HISTORY:** (MONTH/YEAR)	2/20, 2/19, 9/17, 12/16, 9/15, 9/11, 2/11
LOB:	MCL		

This policy has been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the HPSJ Pharmacy and Therapeutic Advisory Committee.

OVERVIEW

Table 1: Available Formulary Agents (*Current as of 01/2020****):***

Class	Generic Name (Brand Name)	Available Strengths	Formulary Status	Notes	Average Cost per 30 days
Iron	Carbonyl Iron (Icar Pediatric, Feosol Caplets)	15 mg chewable Tablets, 45mg Tablets, 15mg/1.25mL Suspension	NF		--
	Iron Dextran Complex (Infed)	50 mg/mL (2 mL) injection, solution	--		$56.75
	Ferric Gluconate (Ferrlecit)	62.5 mg/5ml Vial	--		--
	Iron Sucrose (Venofer)	200 mg/10 mL, 100mg/5mL, 50mg/2.5mL IV Solution	PA	Documentation of appropriate diagnosis is required.	--
	Ferumoxytol (Feraheme)	510 mg/17ml Vial	PA	Documentation of appropriate diagnosis is required.	--
	Ferric Carboxymaltose (Injectafer)	750 mg/15ml Vial	NF		
	Ferric Citrate (Auryxia)	210 mg Tablet	NF		$1,081.40
	Ferrous Fumarate (Hemocyte)	324 mg Tablet (106 mg elemental iron)	NF		$13.38
	Ferrous Gluconate (Fergon)	324 mg Tablet (38 mg elemental iron)	NF		$2.13
	Ferrous Gluconate, preservative free (Ferate)	324 mg Tablet (37.5 mg elemental iron)	NF		$1.48
	Ferrous Sulfate (Ferosul, Fer-In-Sol)	325mg IR Tablet, 324mg DR Tablet, 325mg ER Capsule	--		$1.46
		15mg/mL Drops	--		$6.28
		220mg/5mL Solution	--		$2.05
		300mg/5mL Liquid	--		$116.37
	Polysaccharide-iron Complex (Ferrex-150)	150 mg	NF		--
Erythropoietin Stimulating Agents (ESA)	Epoetin Alfa (Retacrit)	2,000 Unit/mL Injection Solution 3,000 Unit/mL Injection Solution 4,000 Unit/mL Injection Solution 10,000 Unit/mL Injection Solution 40,000 Unit/mL Injection Solution	PA, SP	Reserved for patients who have Hemoglobin (Hgb) < 10 g/dl, TSAT > 20%, and ferritin > 100 ng/ml.	$647.19
	Epoetin Alfa (Epogen)	2,000 Unit/mL Injection Solution 3,000 Unit/mL Injection Solution 4,000 Unit/mL Injection Solution 10,000 Unit/mL Injection Solution	PA, SP	Reserved for patients who have Hemoglobin (Hgb) < 10 g/dl, TSAT > 20%, and	$595.77

		20,000 Unit/mL Injection Solution		ferritin > 100 ng/ml. Must have tried Retacrit first.	
	Epoetin Alfa (Procrit)	2,000 Unit/mL Injection Solution 3,000 Unit/mL Injection Solution 4,000 Unit/mL Injection Solution 10,000 Unit/mL Injection Solution 20,000 Unit/mL Injection Solution 40,000 Unit/mL Injection Solution	NF		--
	Darbepoetin Alfa (Aranesp)	25 mcg/mL Injection Solution 40 mcg/mL Injection Solution 60 mcg/mL Injection Solution 100 mcg/mL Injection Solution 200 mcg/mL Injection Solution 300 mcg/mL Injection Solution 10 mcg/0.4 mL Prefilled Syringe 25 mcg/0.42 mL Prefilled Syringe 40 mcg/0.4 mL Prefilled Syringe 60 mcg/0.3 mL Prefilled Syringe 100 mcg/0.5 mL Prefilled Syringe 150 mcg/0.3 mL Prefilled Syringe 200 mcg/0.4 mL Prefilled Syringe 300 mcg/0.6 mL Prefilled Syringe 500 mcg/mL Prefilled Syringe	NF		--
	Methoxy Polyethylene Glycol-Epoetin Beta (Mircera)	30 mcg/0.3 mL Prefilled Syringe 50 mcg/0.3 mL Prefilled Syringe 75 mcg/0.3 mL Prefilled Syringe 100 mcg/0.3 mL Prefilled Syringe 150 mcg/0.3 mL Prefilled Syringe 200 mcg/0.3 mL Prefilled Syringe	NF		--

EVALUATION CRITERIA FOR APPROVAL/EXCEPTION CONSIDERATION

Below are the coverage criteria and required information for each agent. These coverage criteria have been reviewed and approved by the HPSJ Pharmacy & Therapeutics (P&T) Advisory Committee. For conditions not covered under this Coverage Policy, HPSJ will make the determination based on Medical Necessity as described in HPSJ Medical Review Guidelines (UM06).

Iron Supplements

Ferrous Sulfate (Ferosul)

- ❒ **Coverage Criteria:** None
- ❒ **Limits:** None
- ❒ **Required Information for Approval:** N/A

Iron Dextran (Infed)

- ❒ **Coverage Criteria:** None
- ❒ **Limits:** None
- ❒ **Required Information for Approval:** N/A

Ferric Gluconate (Ferrlecit)

- ❒ **Coverage Criteria:** None
- ❒ **Limits:** None
- ❒ **Required Information for Approval:** N/A

Iron Sucrose (Venofer)

- ❒ **Coverage Criteria:** Reserved for patients with one or more of the following:
  a) Absolute iron deficiency anemia with a ferritin <30µg/L or TSAT <20% with treatment failure or inability to tolerate oral iron.

b) Chronic kidney disease with or without dialysis with ferritin < 500µg/L and TSAT <30% with treatment failure or inability to tolerate oral iron for non-dialysis patients.
c) Chemotherapy-induced anemia with ferritin 30-500µg/L and TSAT <50% in patients receiving ESAs.

- ❒ **Limits:** None
- ❒ **Required Information for Approval:** Updated ferritin and TSAT levels with documented history of treatment failure or inability to tolerate oral iron.

Ferumoxytol (Feraheme)

- ❒ **Coverage Criteria:** Reserved for patients with one or more of the following:
  a) Absolute iron deficiency anemia with a ferritin <30µg/L or TSAT <20% with treatment failure or inability to tolerate oral iron.
  b) Chronic kidney disease with or without dialysis with ferritin < 500µg/L and TSAT <30% with treatment failure or inability to tolerate oral iron for non-dialysis patients.
  c) Chemotherapy-induced anemia with ferritin 30-500µg/L and TSAT <50% in patients receiving ESAs.
- ❒ **Limits:** None
- ❒ **Required Information for Approval:** Updated ferritin and TSAT levels with documented history of treatment failure or inability to tolerate oral iron.

Erythropoietin Stimulating Agents (ESA)

Epoetin Alfa (Retacrit, Epogen)

- ❒ **Coverage Criteria:**
  - Retacrit is reserved for patients who have Hemoglobin (Hgb) < 10 g/dl with TSAT > 20% and serum ferritin > 100 ng/ml at initiation. Hgb should be checked monthly and is not to exceed 11 g/dl. Authorization is for 3 months at a time. For renewal, Hgb must be below 11 g/dL.
  - Epogen is reserved for patients who have Hemoglobin (Hgb) < 10 g/dl with TSAT > 20% and serum ferritin > 100 ng/ml at initiation AND treatment failure or contraindication to Retacrit. Hgb should be checked monthly and is not to exceed 11 g/dl. Authorization is for 3 months at a time. For renewal, Hgb must be below 11 g/dL.
- ❒ **Limits:** Restricted to Diplomat Specialty Pharmacy.
- ❒ **Required Information for Approval:** Submit chart notes including the patient's most recent iron studies and CBC.
- ❒ **Additional Notes:**
  - Epoetin is approved for 3 months at a time.
  - Submission of Hgb levels with the prior authorization renewal request is required and must not exceed 11g/dL.
- ❒ **Non-Formulary:** Procrit

⌗ CLINICAL JUSTIFICATION

Studies have shown that patients who used Epoetin Alfa to target normal levels of Hgb had poor cardiovascular outcomes. These trials showed increases in mortality, nonfatal MI, and hospitalization for CHF. ESA therapy should target a Hemoglobin of less than 11 g/dL. In essence, patients should be treated only to avoid blood transfusion. Iron supplementation is required for most patients with CKD, especially those taking ESAs. Various dosage forms of ferrous sulfate are available on formulary without restriction. Various IV iron agents are now available on our formulary for members unable to take oral iron supplements.

Triage:

1. Duration of Membership
2. Appropriate Diagnosis
3. Current Hemoglobin and Iron studies (TSAT, Ferritin, MCV, Serum Iron)
4. Prescribing Physician Specialty

REFERENCES

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12. Infed (iron dextran) [package insert]. Corona, CA: Watson Pharmaceuticals, Inc.; 2009.
13. Ferrlecit (sodium ferric gluconate complex in sucrose injection) [package insert]. Corona, CA: Watson Pharmaceuticals Inc.; 2006.
14. Venofer (iron sucrose) [package insert]. Shirley, NY: American Regent, Inc.; 2000.
15. Feraheme (ferumoxytol) [package insert]. Waltham, MA: AMAG Pharmaceuticals, Inc.; 2009.
16. Shuoyan Ning, Michelle P. Zeller; Management of iron deficiency. Hematology Am Soc Hematol Educ Program 2019; 2019 (1): 315–322. doi: https://doi.org/10.1182/hematology.2019000034.
17. National Comprehensive Cancer Network. Hematopoietic Growth Factors (Version 2.2020). https://www.nccn.org/professionals/physician_gls/pdf/growthfactors.pdf.

REVIEW & EDIT HISTORY

Document Changes	Reference	Date	P&T Chairman
Creation of Policy	Parenteral Iron Therapeutic Class Review 2-15-11.docx	2/2011	Allen Shek, PharmD BCPS
Update to Policy	ESA Criteria Review 9-20-11.docx	9/2011	Allen Shek, PharmD BCPS
Update to Policy	HPSJ Coverage Policy - Renal - Anemia 2015-09.docx	9/2015	Jonathan Szkotak, PharmD, BCPCS
Update to Policy	HPSJ Coverage Policy - Renal - Anemia 2016-12.docx	12/2016	Johnathan Yeh, PharmD
Update to Policy	HPSJ Coverage Policy - Renal - Anemia 2017-09.docx	9/2017	Johnathan Yeh, PharmD
Update to Policy	HPSJ Coverage Policy - Renal - Anemia 2019-02.docx	2/2019	Matthew Garrett, PharmD
Update to Policy	HPSJ Coverage Policy - Renal - Anemia.docx	2/2020	Matthew Garrett, PharmD
Update to Policy	HPSJ Coverage Policy - Renal - Anemia 2021-02.docx	2/2021	Matthew Garrett, PharmD

Note: All changes are approved by the HPSJ P&T Committee before incorporation into the utilization policy