MEDICATION COVERAGE POLICY

PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE

Health Plan of San Joaquin

POLICY:	ESA/Anemia of Chronic Disease	**P&T DATE:**	2/12/2019
CLASS:	Renal Disease/Genitourinary Disorders	**REVIEW HISTORY:** (MONTH/YEAR)	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 11/2018****):***

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 Sucrose (Venofer)	200 mg/10 mL, 100mg/5mL, 50mg/2.5mL IV Solution	PA	Documentation of appropriate diagnosis is required.	--
	Ferric Citrate (Auryxia)	210 mg Tablet	NF		$1,294.80
	Ferrous Fumarate (Hemocyte)	324 mg Tablet (106 mg elemental iron)	NF		$11.71
	Ferrous Gluconate (Fergon)	324 mg Tablet (38 mg elemental iron)	NF		$1.28
	Ferrous Gluconate, preservative free (Ferate)	324 mg Tablet (37.5 mg elemental iron)	NF		$1.08
	Ferrous Sulfate (Ferosul, Fer-In-Sol)	325mg IR Tablet, 324mg DR Tablet, 325mg ER Capsule	--		$1.74
		15mg/mL Drops	--		$5.82
		220mg/5mL Solution	--		$1.56
		300mg/5mL Liquid	--		$39.91
	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 20,000 Unit/mL Injection Solution	PA, SP	Reserved for patients who have Hemoglobin (Hgb) < 9 g/dl, TSAT > 20%, and ferritin > 100 ng/ml.	--
	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 20,000 Unit/mL Injection Solution	PA, SP	Reserved for patients who have Hemoglobin (Hgb) < 9 g/dl, TSAT > 20%, and ferritin > 100 ng/ml. Must have tried Retacrit first.	$724.20
	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	NF		--

		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			
	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 Sucrose (Venofer)

- ❒ **Coverage Criteria:**
  Venofer is reserved for patients currently on dialysis with recent labs showing TSAT ≤30% and ferritin 500 ng/mL
  OR
  If patient is not on dialysis, documentation that use of less invasive iron supplementation is not sufficient for treatment of the patient's iron deficiency and current labs showing TSAT ≤30% and ferritin ≤500 ng/mL.
- ❒ **Limits:** None
- ❒ **Required Information for Approval:** Documentation that use of less invasive iron supplementation is not sufficient for treatment of the patient's iron deficiency. Iron sucrose (Venofer) is approved 3 months at a time. Submission of TSAT and Ferritin levels with the prior authorization renewal request is required, which shows that TSAT ≤30% and ferritin ≤500 ng/mL.

Erythropoietin Stimulating Agents (ESA)

Epoetin Alfa (Retacrit, Epogen)

- ❒ **Coverage Criteria:**
  - Retacrit is reserved for patients who have Hemoglobin (Hgb) < 9 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) < 9 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. Iron sucrose IV solution is available for members unable to take oral iron supplements; prior authorization is required.

Triage:

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

⌗ REFERENCES

1. FDA approves Retacrit as a biosimilar to Epogen/Procrit. Food and Drug Administration Web Site. https://www.fda.gov/Drugs/InformationOnDrugs/ApprovedDrugs/ucm607723.htm. Updated May 15, 2018. Accessed February 9, 2019.
2. Auerbach M, Winchester J, Wahab A, et al. A randomized trial of three iron dextran infusion methods for anemia in EPO-treated dialysis patients. Am J Kidney Dis. 1998;31(1):81-6.
3. KDIGO Clinical Practice Guidelines for Anemia in Chronic Kidney Disease (2012)
4. Winkelmayer WC, Chang TI, Mitani AA, et al. Longer-term outcomes of darbepoetin alfa versus epoetin alfa in patients with ESRD initiating hemodialysis: a quasi-experimental cohort study. Am J Kidney Dis. 2015;66(1):106-13.
5. Mix TC, Brenner RM, Cooper ME, de Zeeuw D, Ivanovich P, Levey AS, et al. Trial to Reduce Cardiovascular Events with Aranesp Therapy (TREAT): evolving the management of cardiovascular risk in patients with chronic kidney disease. Am Heart J. 2005 Mar;149(3):408-13.
6. Rognoni C, Venturini S, Meregaglia M, Marmifero M, Tarricone R. Efficacy and Safety of Ferric Carboxymaltose and Other Formulations in Iron-Deficient Patients: A Systematic Review and Network Meta-analysis of Randomised Controlled Trials. Clin Drug Investig. 2016;36(3):177-94.
7. Macdougall IC, Strauss WE, Mclaughlin J, Li Z, Dellanna F, Hertel J. A randomized comparison of ferumoxytol and iron sucrose for treating iron deficiency anemia in patients with CKD. Clin J Am Soc Nephrol. 2014;9(4):705-12.
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9. Lawler EV, Bradbury BD, Fonda JR, Gaziano JM, Gagnon DR. Transfusion Burden among Patients with Chronic Kidney Disease and Anemia. Clinical Journal of the American Society of Nephrology : CJASN. 2010;5(4):667-672. doi:10.2215/CJN.06020809.
10. AHFS Drug Information. Iron preparations, oral. AHFS 2018 Drug Information - 58th Ed. Bethesda, MD: American Society of Health-Systems Pharmacists, Inc; 2018
11. Short M.W. et al. Iron Deficiency Anemia: Evaluation and and Management. Am Fam Physician. 2013;87(2):98-104.

⌖ 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

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