

Pharmacy Benefit Determination Policy

Policy Subject: ESA Agents Policy Number: SHS PBD20 Category: Oncology & Anti-infectives Policy Type: <input checked="" type="checkbox"/> Medical <input checked="" type="checkbox"/> Pharmacy Department: Pharmacy	Dates: Effective Date: August 13, 2008 Revision Date: March 29, 2018 Approval Date: April 25, 2018 Next Review Date: April 2019
Product (check all that apply): <input checked="" type="checkbox"/> Group HMO/POS <input checked="" type="checkbox"/> Individual HMO/POS <input checked="" type="checkbox"/> PPO <input checked="" type="checkbox"/> ASO	Clinical Approval By: Medical Directors Peter Graham, MD Pharmacy and Therapeutics Committee Peter Graham, MD

Policy Statement:

Physicians Health Plan, PHP Insurance & Service Company, and Sparrow PHP will cover ESA Agents through the Medical/Pharmacy Benefit based on approval by the Clinical Pharmacist or Medical Director using the following determination guidelines

Drugs and Applicable Coding:

J-code: Epogen/Procrit - J0885; Mircera - J0887-8 (1U/1mcg)

Clinical Determination Guidelines:

Document the following with chart notes

A. Chronic kidney disease (CKD)-induced anemia

1. Diagnosis & severity:
 - a. To ↓ the need for blood transfusions in dialysis & non-dialysis patients
 - b. Hgb ≤ 10gm/dL or HCT ≤ 30%
2. Dosage regimen: IV administration preferred for pts. on dialysis
 - a. Initial:
 - Epogen/Procrit (epoetin alfa IV/SC): 50-100 u/Kg 3x/wk
 - Mircera (methoxy polyethylene glycol-epoetin beta IV/SC): 0.6mg/Kg/2wks or 1.2mg/Kg/4 wks. in stabilized pts
 - b. Titration:
 - Maintain Hgb <11gm/dL
 - Inadequate/lack of response over 12 wk. escalation: Further ↑ not justified
3. Approval
 - a. Initial: 6 mons.
 - b. Re-approval
 - Hgb <11gm/dL or HCT <33%
 - 6 mons.


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- B. Cancer patients on chemotherapy-induced anemia
1. Diagnosis & severity:
 - a. Myelosuppressive chemotherapy in patient w non-myeloid malignancies for palliative intent for >2 mons
 - b. Hgb < 10gm/dL
 2. Dosage regimen:
 - a. Initial: Epogen/Procrit (epoetin alpha IV/SC): 150u/Kg 3x/wk or 40,000u 1x/wk until completion of chemotherapy
 - b. Titration: Maintain Hgb <11gm/dLs
 3. Approve:
 - a. Initial: 3 mons.
 - b. Re-approval: Hgb <11gm/dL; approve 3 more mons.
- C. Zidovudine use in HIV infection-induced anemia
1. Diagnosis & severity:
 - a. Endogenous erythropoietin levels ≤ 500 mu/mL & zidovudine doses $\leq 4,200$ mg/wk
 - b. Hgb ≤ 12 gm/dL
 2. Dosage regimen
 - a. Initial: Epogen/Procrit (epoetin alpha IV/SC) 100u/Kg
 - b. Titration:
 - Maintain Hgb <12g/dL
 - Max dose: Epogen/Procrit (epoetin) 300u/Kg; D/C if Hgb \uparrow not reached in 8 wks
 3. Approval
 - a. Initial: 4 mons
 - b. Re-approval: Hgb ≤ 12 gm/dL
- D. Surgery
1. Indication: To \downarrow allogenic RBC transfusions
 - a. Elective non-cardiac, non-vascular surgery
 - b. Hgb >10 to ≤ 13 g/dL.
 2. Dosage regimen: Epogen/Procrit (epoetin alpha IV/SC): 300u/kg x 15 days, given 10 days pre-op thru 4 days post-op **or** 600u/Kg 1x/wk. x 4 doses, given 3, 2 & 1 wks. pre-op & day of surgery
- E. Non-preferred (Aranesp): Failed or had significant adverse effects to Epogen/Procrit or Mircera
- F. Exclusions:
1. Ca pts receiving hormonal tx, therapeutic biologics, or radiation (unless on concurrent myelosuppressive chemo)
 2. Ca pts receiving myelosuppressive chemo when expected outcome is curative
 3. Surgery pts who are willing to donate autologous blood
 4. Surgery pts undergoing cardiac or vascular surgery
 5. As a substitute for RBC transfusion in pts requiring immediate correction of anemia

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Appendix I: Patient Safety and Monitoring			
Drug	Adverse Reactions	Monitoring	REMS
Erythroid Stimulant Agents Epogen & Procrit (epoetin alpha recombinant)	<ul style="list-style-type: none"> CV: HTN (27.7%), vascular occlusion (8%) MS: Arthralgia (16%) Preg. category: C 	<ul style="list-style-type: none"> CNS: Watch for Premonitory neurological symptoms CV: Blood pressure esp those with pre-existing CV disease Labs: Serum Ferritin pre post tx Hgb weekly until stable then monthly 	<ul style="list-style-type: none"> Medication Guide: Dispensed with product. Web site: Epogen - https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/103234s5360s5364lbl.pdf#page=58 Procrit http://www.fda.gov/downloads/Drugs/DrugSafety/UCM088988.pdf

References and Resources:
<ol style="list-style-type: none"> National Government Services. Erythropoietin Stimulating Agents (ESA) – Supplemental Instructions (DRUG-AC-07-06-02)12/01/07. FDA Alert 11/8/07: Information for Healthcare Professionals: Erythropoiesis Stimulating Agents (ESA). Lexicomp Online®, Lexi-Drugs®, Hudson, Ohio: Lexi-Comp, Inc.; Erythropoietin Alpha, Aranesp & Mircera accessed April 2018

Approved By:	
	4/25/18
Peter Graham, MD – PHP Executive Medical Director	Date
	4/25/18
Human Resources (Kurt Batteen)	Date