

Erythropoiesis Stimulating Agents (ESAs)

Goal(s):

- Cover ESAs according to OHP guidelines and current medical literature.
- Cover preferred products when feasible.

Length of Authorization:

- 12 weeks initially, then up to 12 months
- Quantity limit of 30 day per dispense

Requires PA:

- All ESAs require PA for clinical appropriateness.

Covered Alternatives:

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code	
2. Is this continuation of therapy previously approved by the FFS program?	Yes: Go to #14	No: Go to #3
3. Is this an OHP covered diagnosis?	Yes: Go to #4	No: Current age \geq 21 years: Pass to RPh. Deny; not funded by the OHP Current age < 21 years: Go to #12
4. Is the requested product preferred?	Yes: Go to #6	No: Go to #5
5. Will the prescriber change to a preferred product? <u>Message:</u> <ul style="list-style-type: none"> • Preferred products do not require PA. • Preferred products are evidence-based reviewed for comparative effectiveness and safety by the Pharmacy and Therapeutics (P&T) Committee. 	Yes: Inform prescriber of covered alternatives in class.	No: Go to #6
6. Is the diagnosis anemia due to chronic renal failure ¹ or chemotherapy ^{2,3} ?	Yes: Go to #7	No: Go to #8
7. Is Hgb <10 g/dL or Hct <30% AND Transferrin saturation >20% and/or ferritin >100 ng/mL?	Yes: Approve for 12 weeks with additional approval based upon adequate response.	No: Pass to RPh. Deny; medical appropriateness

Approval Criteria		
8. Is the diagnosis anemia due to HIV ⁴ ?	Yes: Go to #9	No: Go to #10
9. Is the Hgb <10 g/dL or Hct <30% AND Transferrin saturation >20% AND Endogenous erythropoietin <500 IU/L AND If on zidovudine, is dose <4200 mg/week?	Yes: Approve for up to 12 months	No: Pass to RPh. Deny; medical appropriateness
10. Is the diagnosis anemia due to ribavirin treatment ⁵ ?	Yes: Go to #11	No: Pass to RPh. Deny; medical appropriateness
11. Is the Hgb <10 g/dL or Hct <30% AND Is the transferrin saturation >20% and/or ferritin >100 ng/mL AND Has the dose of ribavirin been reduced by 200 mg/day and anemia persisted >2 weeks?	Yes: Approve up to the length of ribavirin treatment.	No: Pass to RPh. Deny; medical appropriateness
12. Is the request for: 1) an FDA approved indication AND 2) is the request for a preferred product or has the patient failed to have benefit with, or have contraindications or intolerance to the preferred products?	Yes: Go to #13	No: Pass to RPh. Deny; medical appropriateness
13. Is there documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc)?	Yes: Approve for up to 12 months	No: Pass to RPh. Deny; medical necessity.
14. Has the patient responded to initial therapy?	Yes: Approve for up to 12 months	No: Pass to RPh. Deny; medical appropriateness

References:

1. National Kidney Foundation. NKF KDOQI Guidelines. *NKF KDOQI Guidelines* 2006. Available at: http://www.kidney.org/professionals/KDOQI/guidelines_anemia/index.htm . Accessed May 25, 2012.
2. Rizzo JD, Brouwers M, Hurley P, et al. American Society of Clinical Oncology/American Society of Hematology Clinical Practice Guideline Update on the Use of Epoetin and Darbepoetin in Adult Patients With Cancer. *JCO* 2010;28(33):4996-5010. Available at: www.asco.org/institute-quality/asco-ash-clinical-practice-guideline-update-use-epoetin-and-darbepoetin-adult. Accessed May 1, 2012.

3. Rizzo JD, Brouwers M, Hurley P, et al. American Society of Hematology/American Society of Clinical Oncology clinical practice guideline update on the use of epoetin and darbepoetin in adult patients with cancer. *Blood*. 2010;116(20):4045-4059.
4. Volberding PA, Levine AM, Dieterich D, et al. Anemia in HIV infection: Clinical Impact and Evidence-Based Management Strategies. *Clin Infect Dis*. 2004;38(10):1454-1463. Available at: <http://cid.oxfordjournals.org/content/38/10/1454>. Accessed May 8, 2012.
5. Recombinant Erythropoietin Criteria for Use for Hepatitis C Treatment-Related Anemia. VHA Pharmacy Benefits Management Strategic Healthcare Group and Medical Advisory Panel. April 2007

P&T Review: 1/19 (JP); 7/16; 5/14; 11/12; 6/12; 2/12, 9/10
Implementation: 10/13/16; 1/1/13; 9/24/12; 5/14/12