Western Health Advantage Pharmacy and Therapeutics Committee
Approved/Revised: December 2009 Reviewed: July 2011
Reviewed by: NorthBay

Erythropoietin, Epoetin alpha (Epogen, Procrit)
JCODE: J3490

OFFICE/HOME HEALTH ADMININISTRATION
or
SELF ADMININISTRATION

APPROVED INDICATIONS

Anemia due to Chronic Renal Failure, including both dialysis and predialysis patients. (If a patient is on dialysis, the drug is usually provided by the dialysis center.) SCr > 2.

Anemia due to Chemotherapy:

- For the treatment of anemia due to the effect of concomitantly administered chemotherapy based on studies that have shown a reduction in the need for RBC transfusions in patients with metastatic, non-myeloid malignancies receiving chemotherapy for a minimum of 2 months. Studies to determine whether PROCRIT. increases mortality or decreases progression free/recurrence-free survival are ongoing:
  - It is not indicated for use in patients receiving hormonal agents, therapeutic biologic products, or radiotherapy unless receiving concomitant myelosuppressive chemotherapy.
  - It is not indicated for patients receiving myelosuppressive therapy when the anticipated outcome is cure due to the absence of studies that adequately characterize the impact on progression-free and overall survival.
  - It is not indicated for the treatment of anemia in cancer patients due to other factors such as iron or folate deficiencies, hemolysis, or gastrointestinal bleeding.
  - It use has not been demonstrated in controlled clinical trials to improve symptoms of anemia, quality of life, fatigue, or patient well-being.

Anemia due to Radiotherapy/Radiation

INDICATIONS THAT REQUIRE PRIOR AUTHROIZATION

HIV Treatment-Related Anemia.:

Require a medication profile noting HIV regimen and Initial: Hct <32% or Hgb less then or equal to 11.
Maintain.: Hct 33-37% and EPO level <500 mU/ml and Serum ferritin level>100 ng/ml or Transferrin saturation >20%

Reduction of allogenic blood transfusion in surgery patients:

Anemic patients (Hgb>11 to <13 g/dl) scheduled for elective, non-cardiac, nonvascular surgery or patients at high risk for peri-operative transfusions with significant, anticipated blood loss.

Patients for whom blood transfusion is not an option.

Patient's with Myelodysplastic Syndrome with a Hgb level less than or equal to 11, a Hct of less than or equal to 30, Hgb 10-12 determined by clinical circumstances, and/or an EPO level of <500. An initial 6-8 week trial period is allowed at 150 units/kg of body wt 3x/week. If there is a > 4.5-5 point rise in the Hct level, EPO may continue to be covered until a Hct level of 36 is obtained. If, after the Hct level of 36 is reached and begins to fall, therapy may be reinstated until a level of 36 is again achieved. When there is no response in the initial trial of 6-8 weeks of therapy, an increased dosage of 300 units/kg of body weight 3x/week is allowed for an additional 6-8 weeks. If there is no improvement in the Hct level of at least 4.5-5 points at the end of the second 8-week period at the higher dose, EPO therapy must be terminated because it is ineffective. If there is a > 4.5-5 point improvement in the Hct level at the end of the 2nd 8 week period at the higher dose, EPO coverage may be continued at the higher dose until the Hct level of 36 is achieved. If the Hct reaches 36 and then falls below that level, EPO may be reinstated at 150 units/kg of body weight until the Hct level of 36 is again achieved.

Anemia due to riboviran therapy

Hematologic malignancies

THE FOLLOWING CRITERIA DO NOT MEET CRITERIA FOR COVERAGE.
Anemia due to:
Cancer without Chemotherapy
Congestive Heart Failure
Porphyria
Postpartum
Prematurity
Rheumatoid Arthritis
Athletic Performance Mgmt
Beta-thalassemia
Blood transfusion reduction
Insulin resistance
Sexual dysfunction
Sickle-cell Anemia
Transfusional iron overload
Serum Epoetin > 500 mU/ml in chronic renal failure or HIV Treatment
Uncontrolled hypertension

DOSING:

Anemia due to CRF:
initially 50-100 U/kg 3x/week,

Anemia due to Chemo:

Anemia in cancer patients on chemotherapy:
Although no specific serum erythropoietin level has been established that predicts which patients would be unlikely to respond to epoetin alfa therapy, treatment of patients with grossly elevated serum erythropoietin levels (eg, more than 200 milliunits/mL) is not recommended.

Hemoglobin should be monitored on a weekly basis in patients receiving epoetin alfa therapy until hemoglobin becomes stable. The dose of epoetin alfa should be titrated for each patient to achieve and maintain the lowest hemoglobin level sufficient to avoid the need for blood transfusion. Do not initiate therapy at hemoglobin levels of 10 g/dL or higher.

Initial dosage:
150 units/kg subcutaneously 3 times per week or 40,000 units subcutaneously weekly.

Dosage adjustment:

Epoetin Alfa Dosage Guidelines for Adult Cancer Patients on Chemotherapy	
Starting dose:	150 units/kg subcutaneously 3 times per week or 40,000 units subcutaneously once weekly
Reduce dose by 25% when:	Hemoglobin reaches a level needed to avoid transfusion or increases > 1 g/dL in any 2-week period.
Withhold dose if:	Hemoglobin exceeds a level needed to avoid transfusion. Restart at 25% below the previous dose when hemoglobin approaches a level for which transfusions may be required.
Increase dose if:	
3-times-per-week dosing: Increase dosage to 300 units/kg 3 times per week if:	Response is not satisfactory (no reduction in transfusion requirements or rise in hemoglobin) after 4 weeks to achieve and maintain the lowest hemoglobin level sufficient to avoid the need for RBC transfusion.
Weekly dosing: Increase to 60,000 units subcutaneously weekly:	Response is not satisfactory (no increase in hemoglobin by ≥ 1 g/dL after 4 weeks of therapy, in the absence of an RBC transfusion) to achieve and maintain the lowest hemoglobin level sufficient to avoid the need for RBC transfusion.
Discontinue:	If after 8 weeks of therapy, there is no response as measured by hemoglobin levels or if transfusions are still required.

Discontinuation of therapy:
Discontinue epoetin alfa if after 8 weeks of therapy there is no response as measured by hemoglobin levels or if transfusions are still required. Discontinue epoetin alfa following completion of a chemotherapy course.

Anemia due to ribavirin therapy

Epoetin 40,000 units once weekly

Anemia due to HIV Treatment:

Initially 200 U/kg 3x/week, titrate to maintain Hct 33-37%. Maximum dose is 14,000 U 3x/week.

Surgery patients:

300 U/kg/day 10 days before surgery, on the day of surgery, and for 4 days after surgery or 600 U/kg/week (21, 14, & 7 days before surgery) plus a fourth dose on the day of surgery.

Myelodysplastic Syndrome:

Initial: 150units/kg given 3x/week x 6-8 weeks.
No response to initial 6-8 week trial: 300units/kg given 3x/week x 6-8 weeks.

Therapeutic Goals

Goal of therapy should be Hemoglobin of 12. Lab values should be timely, less then 2 weeks old.
Hold dose if hemoglobin increase exceeds 12 g/dl or rises by 1g/dl in any 2 week period.

Concurrent iron supplementation is required

Initial Approval 2 months.
Ongoing review every 2 months.
If Hct has not increased in 6 months, reassess therapy.
Dose should be decreased if Hct increased >4% in a 2 week period.

Aranesp (darbepoetin alpha) has no therapeutic advantage over epoetin alpha and must be prior approved for use based on intolerance to the preferred agents.