Prior Authorization Approval Criteria

**Epoetin alfa, darbepoetin alfa**

**Generic name:** Epoetin alfa, darbepoetin alfa

**Brand names:**
- *Epoetin alfa:* Procrit, Epogen
- *Darbepoetin alfa:* Aranesp

**Medication class:** Erythropoetin stimulating agents; stem cell progenitors

**FDA-approved uses:**
- *Epoetin alfa:* Treatment of anemia of chronic renal failure, zidovudine-treated HIV-infected patients, anemia in cancer patients on chemotherapy, and reduction of allogenic blood transfusions in surgery patients

- *Darbepoetin alfa:* Treatment of anemia associated with chronic renal failure, including patients on dialysis and not on dialysis, and for the treatment of anemia in patients with nonmyeloid malignancies where anemia is due to effect of concomitantly administered chemotherapy.

**Black box warnings:**
- Use lowest dose needed to gradually raise hemoglobin to lowest level sufficient to avoid blood transfusions; measure hemoglobin twice a week for 2 – 6 weeks after dosage changes; withhold dose if Hgb exceeds 10 g/dl or rises by ≥ 1 g/dl in any 2-week period.

- Increased risk of thrombotic events and/or death in patients with CRF, cancer patients on chemotherapy, and surgical candidates.

- In Cancer patients: Shortened survival and/or increased risk of tumor progression or recurrence in some patients with breast, non-small cell lung, head and neck, lymphoid, and cervical cancers. Because of these risks, prescribers and hospitals must enroll in and comply with the ESA APPRISE Oncology Program to prescribe and/or dispense Epoetin to patients with cancer. In cancer patients, use ESAs for treatment of anemia due only to concomitant myelosuppressive chemotherapy. ESAs are not indicated for patients receiving myelosuppressive chemotherapy when the anticipated outcome is cure. **Discontinue** after completion of a chemotherapy course.

- Should not be used in patients with uncontrolled hypertension. Closely monitor blood pressure in patients with controlled hypertension.

- In renal failure patients, individualize dosing to achieve and maintain hemoglobin levels within the range of 10 to 12 g/dl. Patients titrated to higher target hemoglobin levels experienced greater risks of death and serious cardiovascular events.

- In perisurgical patients, Procrit increased the incidence of deep venous thromboses in patients not receiving prophylactic anticoagulation. Consider DVT prophylaxis.
Duration of therapy: Sufficient to decrease/eliminate the need for transfusions; not to exceed a hemoglobin level of 12 g/dl for any of the ESA products for all indications

Cost (based on AWP 2010):
- CRF:
  - Aranesp (0.45mcg/kg/wk, 70 kg patient): $197/week
  - Procrit/Epogen (10,000 units/week): $152/week
- Chemo-induced anemia:
  - Aranesp (2.25 mcg/kg/wk, 70 kg patient): $984/week
  - Procrit/Epogen (40,000 units/week): $607/week

Criteria for use (bullet points below are all inclusive unless otherwise noted):
- The indicated diagnosis (including any applicable labs and/or tests) must be supported by documentation from the patient’s medical records.
- Patients must have a hematocrit of less than 30% or a hemoglobin level less than 10g/dL prior to therapy.
- Patients with anemia and having hematocrit levels greater than 30% and hemoglobin levels greater than 10 g/dL must have supporting documentation in the medical record that provides evidence of the presence of significant comorbidity, such as severe COPD or cardiac disease, that warrants a need for higher hematocrit and hemoglobin levels.
- If approved, Procrit must be used. Aranesp or Epogen will only be approved if patient is intolerant of Procrit.
- Must have clinically documented chronic renal failure:
  - Anemia in chronic renal failure patients who are receiving dialysis or not receiving dialysis

OR
- Must have clinically documented anemia due to concomitant myelosuppressive chemotherapy for metastatic non-myeloid malignancies
  - Provider must be enrolled in the ESA APPRISE Oncology program
  - Patient must sign ESA APPRISE Oncology Patient and Healthcare Professional (HCP) Acknowledgement Form to document that the healthcare provider discussed the risks of Epoetin with the patient.
  - Anticipated outcome of chemotherapy is NOT cure
  - Patient is receiving chemotherapy or within 8 weeks of the final chemotherapy dose

OR
- Must have clinically documented HIV-infection and anemia is due to zidovudine therapy

OR
- Must be an anemic surgery patient with all of the following:
  - Surgery is elective, non cardiac, non-vascular
  - Perioperative hemoglobin > 10 to ≤ 13 g/dL
  - At risk for perioperative transfusions due to significant anticipated blood loss (this includes patients who are expected to require 2 units of blood and who are not able or willing to participate in an autologous blood donation program)

OR
- Must have clinically documented myelopdysplasia or myelodysplastic syndromes

OR
- Must have clinically documented Hepatitis C
  - Must have Hep C treatment-induced anemia

The criteria listed above applies to Fallon Health Plan and its subsidiaries.
Criteria for continuation of therapy for indications other than surgery (bullet points below are all inclusive unless otherwise noted):

- The indicated diagnosis (including any applicable labs and/or tests) must be supported by documentation from the patient’s medical records.
- After 12 weeks of treatment, the effectiveness must be demonstrated by an improvement in the hematocrit and hemoglobin levels or by a significant decrease in transfusion requirements.
- Must have hematocrit maintained below 36% and/or hemoglobin maintained below 12 g/dl.
  - If an individual lab result exceeds 36 (HCT) and/or 12 (HGB), then there must be a protocol for erythropoietin dose reduction/withholding and subsequent lab values below 36 (HCT) and/or 12 (HGB).
- For cancer patients on myelosuppressive chemotherapy, the time since final dose of myelosuppressive chemotherapy is less than 8 weeks.

* Hemoglobin and hematocrit levels that exceed 12 and 36, respectively, may be cause for reversal of respective payment upon retro review.

Physician must provide FCHP with the following:

- Diagnosis
- Dates and results of most recent hematocrit and hemoglobin
- Number of units needed to administer
- Expected duration of therapy

Contraindications:

- Patients with uncontrolled hypertension
- Pure red cell aplasia (PRCA) that begins after treatment with erythropoietin protein drugs
- Serious allergic reactions to erythropoietin protein drugs
- Procrit and Epogen: Use of the multi-dose vials in neonates, infants, pregnant women, and nursing mothers

Fallon Health Pharmacy and Therapeutics Committee approval: _______________________

Date: ______________________

Adopted: 09/10/08

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