Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	August 19, 2019 July 7, 2020

RETACRIT™ (epoetin alfa-epbx)

LENGTH OF AUTHORIZATION: UP TO SIX MONTHS

REVIEW CRITERIA:

****Trial and failure to therapy of a preferred medication (e.g. Aranesp or Epogen) is required for each indication listed below**:

Anemia associated with chronic kidney disease (CKD) if patient is not on dialysis or receiving home dialysis (Approve for 6 months):

- **Initial Therapy – Patient must meet all requirements below:**
  - Hemoglobin < 10 g/dL Transferrin saturation ≥ 20% and Serum Ferritin ≥ 100ng/mL.
  - Lab data within 2 months of prior authorization (PA) submission.
- **Continuation of Therapy:**
  - Hemoglobin ≤ 11 g/dL Transferrin saturation ≥ 20% and Serum Ferritin ≥ 100ng/mL.
  - Lab data within 2 months of PA submission.

Anemia associated with chemotherapy: (Approve for 6 months)

- **Initial Therapy:**
  - No existing history of iron or folate deficiency, hemolysis, or gastrointestinal bleeding.
  - Hemoglobin < 10 g/dL Transferrin saturation ≥ 20% and Serum Ferritin ≥ 100ng/mL.
  - Must be on or initiating chemotherapy.
- **Continuation of Therapy:**
  - No existing history of iron or folate deficiency, hemolysis, or gastrointestinal bleeding.
  - Hemoglobin ≤ 12 or lowest level sufficient to avoid transfusion
  - Transferrin saturation ≥ 20% Serum Ferritin ≥ 100ng/mL

Anemia associated with human immunodeficiency virus (Approve for 3 months):

- **Initial Therapy:**
  - No existing history of iron or folate deficiency, hemolysis, or gastrointestinal bleeding.
  - Hemoglobin < 13 g/dL in men and < 12 g/dl in women.
  - Transferrin saturation ≥ 20% and Serum Ferritin ≥ 100ng/mL
- **Continuation of Therapy:**
  - Hemoglobin < 13 g/dL in men and < 12 g/dl in women

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- Transferrin saturation ≥ 20% and Serum Ferritin ≥ 100ng/mL

To reduce the need for allogenic blood transfusions in anemic patients scheduled to undergo elective, non-cardiac, nonvascular surgery (Approve no more than 15 doses).

- Must be unwilling to donate blood.
- Patient must have a hemoglobin > 10 and ≤ 13 g/dL.
- Must be receiving iron supplementation.

Supplemental iron therapy is recommended for all patients whose serum ferritin is below 100 mcg/L or whose serum transferrin saturation is below 20%.

Epogen is not intended for patients who require immediate correction of severe anemia. Epogen may remove the need for maintenance transfusions but is not a substitute for emergency transfusion or treatment of other causes of anemia, such as iron deficiency, underlying infectious, inflammatory, or malignant processes, occult blood loss, underlying hematologic diseases, folic acid, vitamin B-12 deficiency, or hemolysis.

DOSING INFORMATION:

Chronic Kidney Disease

Starting Dose:

- **For adult patients with CKD not on dialysis,** the recommended starting dose:
  - 50 to 100 units/kg, 3 times weekly intravenously or subcutaneously.
- **For pediatric patients with CKD not on dialysis** the recommended starting dose:
  - 50 units/kg, 3 times weekly intravenously or subcutaneously.

Starting Dose:

- **For adult patients with CKD on dialysis**, the recommended starting dose:
  - 50 to 100 units/kg, 3 times weekly intravenously or subcutaneously.
  - The intravenous route is recommended for patients on hemodialysis.
- **For pediatric patients with CKD on dialysis**, the recommended starting dose:
  - 50 units/kg, 3 times weekly intravenously or subcutaneously.
  - The intravenous route is recommended for patients on hemodialysis.

Zidovudine-treated HIV-infected Patients

Starting Dose:

- The recommended starting dose in adults is 100 units/kg, 3 times weekly intravenously or subcutaneously.
- The recommended starting dose in pediatrics is 50-400 units/kg, 2-3 times per week intravenously or subcutaneously.

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Cancer Patients on Chemotherapy

Starting Dose:

- The recommended starting dose in adults:
  - 150 units/kg subcutaneously 3 times per week until completion of a chemotherapy course OR
  - 40,000 units subcutaneously weekly until completion of a chemotherapy course.
- The recommended starting dose in pediatrics:
  - 600 units/kg intravenously weekly until completion of a chemotherapy course.

Surgery Patients

Recommended Dose:

- 300 units/kg per day subcutaneously for 15 days total: administered daily, starting 10 days before surgery, and continue until 4 days after surgery; OR
- 600 units/kg subcutaneously every week for 4 doses, administered 21 days, 14 days, 7 days before surgery and on the day of surgery.