Aranesp® (darbepoetin alfa)

LENGTH OF AUTHORIZATION: SIX MONTHS

REVIEW CRITERIA:

Anemia associated with chronic kidney disease if patient is not on dialysis:

- **Initial Therapy:**
  - Hemoglobin < 10g/dL, Transferrin saturation ≥ 20% and Serum Ferritin ≥ 100ng/mL.
  - Lab data within 2 months of PA submission.

- **Continuation of Therapy:**
  - Hemoglobin ≤ 10 g/dL, Transferrin saturation ≥ 20% and Serum Ferritin ≥ 100ng/mL.
  - Lab data within 2 months of PA submission.

Anemia associated with chronic kidney disease if patient is receiving home dialysis:

- **Initial Therapy:**
  - Hemoglobin < 10 g/dL, Transferrin saturation ≥ 20% and Serum Ferritin ≥ 100ng/mL.
  - Lab data within 2 months of 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:

- **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 < 10 g/dL or lowest level sufficient to avoid transfusion.
  - Transferrin saturation ≥ 20% and Serum Ferritin ≥ 100ng/mL.

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

**Chronic Kidney Disease Patients**

Starting Dose:

- **For adult patients not on dialysis** the recommended starting dose:
  - 0.45 mcg/kg intravenously or subcutaneously given once every four weeks.
- **For pediatric patients not on dialysis** the recommended starting dose:
  - 0.45 mcg/kg intravenously or subcutaneously weekly OR
  - 0.75 mcg/kg once every 2 weeks.
- **For patients on dialysis** the recommended starting dose:
  - 0.45 mcg/kg intravenously or subcutaneously weekly OR
  - 0.75 mcg/kg intravenously or subcutaneously once every 2 weeks.
  - The intravenous route is recommended for patients on hemodialysis.
- **For pediatric patients on dialysis** the recommended dose:
  - 0.45 mcg/kg intravenously or subcutaneously weekly.
  - The intravenous route is recommended for patients on hemodialysis.

**Cancer Patients Receiving Chemotherapy**

Starting Dose: The recommended starting dose:

- 2.25 mcg/kg subcutaneously weekly OR
- 500 mcg subcutaneously once every 3 weeks.