



Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	January 22,2010, July 25, 2011, April 12,2012, March 31, 2015, July 21, 2017, April 2, 2018, June 8, 2018, October 29, 2018, July 24, 2019

## **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  $\geq$  20% and Serum Ferritin  $\geq$  100ng/mL.
  - Lab data within 2 months of PA submission.
- **Continuation of Therapy:**
  - Hemoglobin  $\leq$  10 g/dL, Transferrin saturation  $\geq$  20% and Serum Ferritin  $\geq$  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  $\geq$  20% and Serum Ferritin  $\geq$  100ng/mL.
  - Lab data within 2 months of PA submission.
- **Continuation of Therapy:**
  - Hemoglobin  $\leq$  11 g/dL, Transferrin saturation  $\geq$  20% and Serum Ferritin  $\geq$  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  $\geq$  20% and Serum Ferritin  $\geq$  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  $\geq$  20% and Serum Ferritin  $\geq$  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%.**



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## 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:
  - 0.45mcg/kg intravenously or subcutaneously weekly **OR**
  - 0.75mcg/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:
  - 0.45mcg/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.