



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

Aranesp® (darbepoetin alfa)

LENGTH OF AUTHORIZATION: SIX MONTHS

REVIEW CRITERIA:

****Trial and failure to therapy of a preferred medication is required for each indication listed below:**

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.