



Aranesp® (darbepoetin alfa) Injection

When requesting Aranesp® (darbepoetin alfa) injection for non-oncology anemia, the individual requiring treatment must be diagnosed with the following FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-approved Non-oncology Indication

Aranesp is indicated for the treatment of anemia due to chronic kidney disease (CKD) in patients on dialysis and patients not on dialysis.

Coverage Guidelines

Anemia in Patients with Chronic Kidney Disease (CKD)

- An individual is on dialysis
- OR
- An individual is not on dialysis and must meet the following criteria:
 - Has adequate iron stores OR is currently receiving iron therapy
 - *For an initial authorization* – must have a hemoglobin <10.0 g/dL for 18 years of age or older OR a hemoglobin ≤11.0 g/dL for less than 18 years of age
 - *For individuals who are currently receiving an erythropoiesis-stimulating agent (e.g., an epoetin alfa product [e.g., Epogen, Procrit, or Retacrit], a darbepoetin alfa product [e.g., Aranesp], a methoxy polyethylene glycol-epoetin beta product [e.g., Mircera])* – must have a hemoglobin <11.5 g/dL for 18 years of age or older OR a hemoglobin ≤12.0 g/dL for less than 18 years of age.

Approval Duration: 12 monthsDosing Recommendations

Recommended starting dose for patients with chronic kidney disease (CKD) on dialysis

- 0.45 mcg/kg intravenously or subcutaneously weekly, OR
- 0.75 mcg/kg intravenously or subcutaneously every 2 weeks
- Intravenous route is recommended for patients on hemodialysis

Recommended starting dose for patients with CKD not on dialysis

- 0.45 mcg/kg intravenously or subcutaneously at 4 week intervals

Recommended starting dose for pediatric patients with CKD

- 0.45 mcg/kg intravenously or subcutaneously weekly
- Patients with CKD not on dialysis may also be initiated at 0.75 mcg/kg every 2 weeks

References

1. Aranesp® injection for intravenous or subcutaneous use [prescribing information]. Thousand Oaks, CA: Amgen, Inc.; January 2019.
2. Kidney Disease: Improving Global Outcomes (KDIGO) Anemia Work Group. KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease. *Kidney Int.* 2012;2(Suppl):279-335.
3. Darbepoetin alfa (Aranesp®). Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. [Updated; March 9, 2021; Accessed July 27, 2021].