

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 Indications

- Anemia associated with chronic kidney disease (CKD) in individuals on dialysis and individuals not on dialysis

Coverage Guidelines

Anemia in Patients with Chronic Kidney Disease (CKD):

Approve if the patient meets the following criteria (A or B)

- A) Initial Therapy- Approve if the patient meets the following criteria (i and ii)
- i) The patient meets one of the following (a or b)
 - a) The patient is ≥ 18 years of age with a hemoglobin (Hgb) is < 10.0 g/dL; OR
 - b) The patient is < 18 years of age with a hemoglobin ≤ 11 g/dL; AND
 - ii) The patient meets one of the following (a or b)
 - a) The patient is currently receiving iron therapy; OR
 - b) The patient has adequate iron stores.
- B) Patient is currently receiving an erythropoiesis-stimulating agent (ESA). Note: Examples of erythropoiesis-stimulating agents include an epoetin alfa product (e.g., Epogen, Procrit, or Retacrit), a darbepoetin alfa product (e.g., Aranesp), or a methoxy polyethylene glycol-epoetin beta product (e.g., Mircera). Approve if the patient meets the following criteria (i and ii):
- i) The patient meets one of the following (a or b)
 - a) The patient is ≥ 18 years of age with a hemoglobin < 11.5 g/dL; OR
 - b) The patient is < 18 years of age with a hemoglobin ≤ 12.0 g/dL; AND
 - ii) The patient meets one of the following (a or b):
 - a) The patient is currently receiving iron therapy; OR
 - b) The patient has adequate iron stores.

Approval Duration: 12 months

Dosing Requirements

Anemia in Patients with Chronic Kidney Disease (CKD) who are on Dialysis:

Approve the following dosing regimens (A or B):

- A) The dose meets the following (i and ii):

- i) Each dose is $\leq 0.45\text{mcg/kg}$; AND
- ii) Each dose is given no more frequently than once every week: OR
- B) The dose meets the following (i and ii):
 - i) Each dose is $\leq 0.75\text{mcg/kg}$; AND
 - ii) Each dose is given no more frequently than once every 2 weeks

Anemia in Patients with Chronic Kidney Disease (CKD) who are not on Dialysis:

Approve the following dosing regimens (A or B)

- A) Patients ≥ 18 years of age. Approve if the dose meets the following (i and ii)
 - i) Each dose is $\leq 0.45\text{ mcg/kg}$; AND
 - ii) Each dose is given no more frequently than once every 4 weeks; OR
- B) Patients < 18 years of age. Approve if the dose meets the following (i and ii):
 - i) Each dose is $\leq 0.75\text{ mcg/kg}$; AND
 - ii) Each dose is given no more frequently than once 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 Inter.* 2012;2(Suppl):279-335. Available at: http://www.kdigo.org/clinical_practice_guidelines/pdf/KDIGO-Anemia%20GL.pdf. Accessed on June 22, 2018.

Other References Utilized

1. Solomon SD, Uno H, Lewis EF, et al, for the Trial to Reduce Cardiovascular Events with Aranesp Therapy (TREAT) Investigators. Erythropoietic response and outcomes in kidney disease and type 2 diabetes. *N Engl J Med.* 2010;363:1146-1155.
2. Schaefer F, Hoppe B, Jungraithmayr T, et al. Safety and usage of darbepoetin alfa in children with chronic kidney disease: prospective registry study. *Pediatr Nephrol.* 2016;31:443-453.
3. Blumer J, Berg S, Adamson PC, et al. Pharmacokinetic evaluation of darbepoetin alfa for the treatment of pediatric patients with chemotherapy-induced anemia. *Pediatr Blood Cancer.* 2007;49:687-693.
4. Warady BA, Barcia J, Benador N, et al. De novo weekly and biweekly darbepoetin alfa dosing in pediatric patients with chronic kidney disease. *Pediatr Nephrol.* 2018;33(1):125-137.