

Epogen[®], Procrit[®], Retacrit[®] (epoetin alfa) injection

When requesting Epogen[®], Procrit[®], Retacrit[®] (epoetin alfa) injection for non-oncology anemia, the individual requiring treatment must be diagnosed with one of the following FDA-approved indications and meet the specific coverage guidelines and applicable safety criteria for the covered indications.

FDA-Approved Non-Oncology Indications

- Anemia associated with chronic kidney disease (CKD) in individuals on dialysis and individuals not on dialysis
- Anemia associated with zidovudine use in HIV-infected patients
- Pre-surgical use to reduce allogeneic blood transfusions

Coverage Guidelines

Anemia associated with Chronic Kidney Disease (CKD)

Patient must meet the following criteria (A or B):

- A) Initial Therapy- Approve if the patient meets the following criteria (i and ii)
- The patient meets one of the following (a or b)
 - The patient is ≥ 18 years of age with a hemoglobin < 10 g/dL; OR
 - The patient is < 18 years of age with a hemoglobin ≤ 11 g/dL; AND
 - The patient meets one of the following (a or b):
 - The patient is currently receiving iron therapy; OR
 - The patient has adequate iron stores.
- B) Patient is currently receiving an erythropoiesis-stimulating agent (ESA): Examples of erythropoiesis-stimulating agents include epoetin alfa product (e.g., Epogen, Procrit, or Retacrit), a darbepoetin alfa products (e.g., Aranesp), or methoxy polyethylene glycol-epoetin beta product (e.g., Mircera). Approve if the patient meets the following criteria (i and ii):
- The patient meets one of the following (a or b)
 - The patient is ≥ 18 years of age with a hemoglobin < 11.5 g/dL; OR
 - The patient is < 18 year of age with a hemoglobin ≤ 12 g/dL;
 - The patient meets one of the following (a or b):
 - The patient is currently receiving iron therapy; OR
 - The patient has adequate iron stores.

Approval Duration: 12 months

Anemia associated with zidovudine use in HIV-infected patients

The patient must meet the following criteria (A or B):

- A) Initial Therapy- Approve if the patient meets the following criteria (i, ii, and iii)
- The patient meets one of the following (a or b)
 - The patient has a hemoglobin < 10 g/dL; OR
 - The patient has a serum erythropoietin level is ≤ 500 mU/ml; AND
 - The patient is currently receiving zidovudine therapy; AND
 - The patient meets one of the following (a or b):
 - The patient is currently receiving iron therapy; OR

- b) The patient has adequate iron stores.
- B) Patient is currently receiving an erythropoiesis-stimulating agents (ESA). Note; Examples of erythropoiesis-stimulating agent include an epoetin alfa product (e.g., Epogen, Procrit, or Retacrit), or a darbepoetin alfa product (e.g., Aranesp). Approve if the patient meets the following criteria (i, ii, and iii);
 - i) The patient has a hemoglobin ≤ 12 g/dL; AND
 - ii) The patient is currently receiving zidovudine therapy; AND
 - iii) 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

Pre-surgical use to reduce allogeneic blood transfusions

Approve if the patient meets the following criteria (A, B, C, and D):

- A) Hemoglobin is ≤ 13 g/dL; AND
- B) The surgery is elective, nonvascular, and noncardiac; AND
- C) The patient is not willing or able to donate autologous blood prior to surgery; AND
- D) The patient meets one of the following (i or ii);
 - i) The patient is currently receiving iron therapy; OR
 - ii) The patient has adequate iron stores.

Approval Duration: 1 month

Dosing Information

A) Anemia associated with chronic kidney disease

- i) Patient is ≥ 18 years of age. Approve if the dose meets the following (a and b):
 - a) The dose is ≤ 100 Units/kg; AND
 - b) Each dose is given no more frequently than 3 times a week; OR
- ii) Patient is < 18 years of age. Approve if the dose meets the following (a and b)
 - a) Each dose is ≤ 50 Units/kg; AND
 - b) Each dose is given not more than 3 times per week

B) Zidovudine-associated anemia in HIV-infected patients

- i) Approve the following dosing regimens (a or b):
 - a) Patients ≥ 18 years of age. Approve if the dose meets the following (1 and 2)
 - (1) Each dose is ≤ 300 Units/kg; AND
 - (2) Each dose is given no more frequently than 3 times a week; OR
 - b) Patient is < 18 of age. Approve if the dose meets the following (1 and 2);
 - (1) Each dose is ≤ 400 Units/kg; AND
 - (2) Each dose is given no more frequently than 3 times a week

C) Reduction of allogenic blood transfusion requirements in anemic surgery patients

- i) Approve the following dosing regimens (a or b):
 - a) Approve if the dose meets the following (1 and 2)
 - (1) Each dose is ≤ 300 U/kg per day; AND
 - (2) The total amount of doses is < 15 ; OR
 - b) Approve if the dose meets the following (1 and 2):
 - (1) Each dose is ≤ 600 Units/kg per day; AND

(2) The total amount of doses is ≤ 4 .

References

1. Procrit® injection for intravenous or subcutaneous use [prescribing information]. Horsham, PA: Janssen; July 2018.
2. Epogen® injection for intravenous or subcutaneous use [prescribing information]. Thousand Oaks, CA: Amgen, Inc.; July 2018.
3. Retacrit™ injection for subcutaneous or intravenous use [prescribing information]. New York, NY and Lake Forest, IL: Pfizer and Hospira; January 2019.
4. Fischl M, Galpin JE, Levine JD, et al. Recombinant human erythropoietin for patients with AIDS treated with zidovudine. *N Engl J Med*. 1990;322:1488-1493.
5. 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. Available at: <https://kdigo.org/wp-content/uploads/2016/10/KDIGO-2012-Anemia-Guideline-English.pdf>. Accessed on June 19, 2019.

Other References Utilized

1. Staples AO, Wong CS, Smith JM, et al. Anemia and risk of hospitalization in pediatric chronic kidney disease. *Clin J Am Soc Nephrol*. 2009;4:48-56.