

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

Approved Non-Oncology Off-Label Compendial Uses

None

Coverage Guidelines

Anemia associated with chronic kidney disease (CKD)

Initial authorization:

- The pretreatment hemoglobin (Hgb) level is less than 10 g/dL
- Serum ferritin is greater than or equal to 100 mcg/L OR serum transferrin saturation is greater than or equal to 20% OR individual is receiving supplemental iron
- All other causes of anemia are ruled out or corrected (e.g., vitamin deficiency, metabolic conditions, bleeding, etc.)
- The individual does **not** have any of the following conditions:
 - Uncontrolled hypertension
 - Pure red cell aplasia that begins after treatment with ESA

Reauthorization:

- Serum ferritin is greater than or equal to 100 mcg/L OR serum transferrin saturation is greater than or equal to 20% OR individual is receiving supplemental iron
- The patient has adequately responded to epoetin alfa therapy (i.e. an increase in hemoglobin of at least 1 g/dL after at least 12 weeks of therapy)
- The current hemoglobin level is less than 12 g/dL
- The individual does **not** have any of the following conditions:
 - Uncontrolled hypertension
 - Pure red cell aplasia that begins after treatment with ESA

Approval (initial and reauthorization) duration is 6 months

Anemia associated with zidovudine use in HIV-infected patients

Initial authorization:

- The pretreatment hemoglobin (Hgb) level is less than 10 g/dL
- Serum ferritin is greater than or equal to 100 mcg/L OR serum transferrin saturation is greater than or equal to 20% OR individual is receiving supplemental iron
- All other causes of anemia are ruled out or corrected (e.g., vitamin deficiency, metabolic conditions, bleeding, etc.)
- The individual does **not** have any of the following conditions:
 - Uncontrolled hypertension
 - Pure red cell aplasia that begins after treatment ESA
- Zidovudine dose is less than or equal to 4,200mg/week
- Endogenous serum erythropoietin (EPO) level is less than or equal to 500 mU/mL

Reauthorization:

- Serum ferritin is greater than or equal to 100 mcg/L OR serum transferrin saturation is greater than or equal to 20% OR individual is receiving supplemental iron
- All other causes of anemia are ruled out or corrected (e.g., vitamin deficiency, metabolic conditions, bleeding, etc.)
- The individual does **not** have any of the following conditions:
 - Uncontrolled hypertension
 - Pure red cell aplasia that begins after treatment with ESA
- Zidovudine dose is less than or equal to 4,200mg/week
- The patient has adequately responded to epoetin alfa therapy after at least 8 weeks at 300 units/kg
- The current hemoglobin level is less than 12 g/dL

Approval (initial and reauthorization) duration is 6 months

Pre-surgical use to reduce allogeneic blood transfusions

- The individual is undergoing elective, noncardiac, nonvascular surgery
- The pretreatment hemoglobin (Hgb) level is greater than 10 g/dL but less than or equal to 13 g/dL
- The individual is at high risk for significant perioperative blood loss requiring allogeneic blood transfusions
- Serum ferritin is greater than or equal to 100 mcg/L OR serum transferrin saturation is greater than or equal to 20% OR individual is receiving supplemental iron
- All other causes of anemia are ruled out or corrected (e.g., vitamin deficiency, metabolic conditions, bleeding, etc.)
- The individual does **not** have any of the following conditions:
 - Uncontrolled hypertension
 - Pure red cell aplasia that begins after treatment with ESA

Approval duration is 2 months

Dosing Information

- Anemia associated with chronic kidney disease
 - o Adult: 50-100 units/kg IV or subcutaneously 3 times weekly
 - o Pediatric receiving dialysis: 50 units/kg 3 times weekly
- Zidovudine-associated anemia in HIV-infected patients
 - o Initial: 100 units/kg IV or subcutaneously 3 times weekly
- Reduction of allogenic blood transfusion requirements in anemic surgery patients
 - o 300 units/kg given subcutaneous injection once daily for 10 days prior to surgery, on the day of surgery, and for 4 days after surgery
 - o Alternative: 600 units/kg given subcutaneously once weekly for 3 weeks prior to surgery (i.e. days 21, 14, and 7 before surgery) with an additional dose given on the day of surgery

References

1. Epogen® prescribing information. Thousand Oaks, CA: Amgen, Inc.: September 2017. Accessed June 25, 2018.
2. Procrit® prescribing information. Horsham, PA: Janssen Products, LP.: September 2017. Accessed June 25, 2018.
3. Retacrit® prescribing information. Lake Forest, IL: Hospira, Inc.: May 2018. Accessed June 25, 2018.
4. Klasco RK (Ed): DRUGDEX® system. Thomson Micromedex, Greenwood Village, CO. Accessed June 25, 2018.