SmartHealth

Ascension

# Epoetin alfa

## (Epogen® or Procrit®) J0885, J0886, Q4081

### Covered with prior authorization

**Epoetin alfa (Epogen® or Procrit®) may be authorized when the following criteria are met:**

**Anemia due to Chronic Kidney Disease**

- Diagnosis of anemia of CKD (dialysis and non-dialysis individuals); **AND**
- Prescribed by or in consultation with a hematologist or nephrologist; **AND**
- Adequate iron stores as indicated by current (within the last 3 months) serum ferritin level ≥ 100 mcg/L or serum transferrin saturation ≥ 20%; **AND**
- Pretreatment hemoglobin level < 10 g/dL; **AND**
- Dose is age- and condition-appropriate:
    - Adult: 50 to 100 Units/kg 3 times weekly
    - Pediatric: 50 Units/kg 3 times weekly
    - Individualize maintenance dose.
    - Intravenous route recommended for individuals on hemodialysis.

**OR**

**Anemia due to Zidovudine in HIV-infected Patients**

- Diagnosis of zidovudine induced anemia; **AND**
- Prescribed by or in consultation with a hematologist or HIV specialist; **AND**
- Individual is HIV-positive; **AND**
- Dose of zidovudine is ≤ 4,200 mg/week; **AND**
- Endogenous serum erythropoietin levels ≤ 500 mUnits/mL; **AND**
- Adequate iron stores as indicated by current (within the last 3 months) serum ferritin level ≥ 100 mcg/L or serum transferrin saturation ≥ 20%; **AND**
- Pretreatment hemoglobin level < 10 g/dL; **AND**
- Dose is 100 Units/kg 3 times weekly.

**OR**

**Anemia due to Chemotherapy in Patients with Cancer**

- Request is for use in solid or non-myeloid malignancies in members receiving myelosuppressive chemotherapy without curative intent; **AND**
- Prescribed by or in consultation with a hematologist or oncologist; **AND**
- Age ≥ 5 years; **AND**
- Adequate iron stores as indicated by current (within the last 3 months) serum ferritin level ≥ 100 mcg/L or serum transferrin saturation ≥ 20%; **AND**
- Pretreatment hemoglobin < 10 g/dL; **AND**
- Dose is age-appropriate:
    - Adults:40,000 Units weekly or 150 Units/kg 3 times weekly
    - Pediatrics: 600 Units/kg intravenously weekly.

Developed by: Medical Specialty Prior Authorization Team, April 2022

Approved by: Ambulatory Care Expert Review Panel, April 2022; Therapeutic Affinity Group, May 2022

**OR**
**Reduction of Allogeneic Red Blood Cell Transfusions in Patients Undergoing Elective, Noncardiac, Nonvascular Surgery:**

- Individual is at high risk for perioperative blood loss from elective, noncardiac, nonvascular surgery; **AND**
- Perioperative hemoglobin > 10 to ≤ 13 g/dL; **AND**
- Adequate iron stores as indicated by current (within the last 3 months) serum ferritin level ≥ 100 mcg/L or serum transferrin saturation ≥ 20%; **AND**
- Individual is unwilling or unable to donate autologous blood pre-operatively; **AND**
- Dose does not exceed:
    - 300 Units/kg administered daily for a total of 15 doses;
    - 600 Units/kg for a total of 4 doses.

**AND**

- Individual has had a trial of and inadequate response or intolerance to the biosimilar product (Retacrit), unless contraindicated or clinically significant adverse effects are experienced; **OR**
- Procrit® or Epogen® are FDA-approved for the prescribed indication while the biosimilar product is not.

**Exclusion criteria:**

- Product use for non-FDA approved indications or indications not supported by industry-accepted guidelines;
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use;
- Significant individual risk: erythropoiesis-stimulating agents (ESAs) have black box warnings for an increased risk of death, myocardial infarction, stroke, venous thromboembolism, thrombosis of vascular access, and tumor progression or recurrence;
- Patients with cancer receiving hormonal agents, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy;
- Patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure;
- Patients scheduled for surgery who are willing to donate autologous blood;
- Patients undergoing cardiac or vascular surgery;
- As a substitute for RBC transfusions in individuals who require immediate correction of anemia;
- Continued use when the hemoglobin level exceeds 11 g/dL (unless target varies for clinical condition);
- Individuals with uncontrolled hypertension;
- Use beyond 12 weeks of continuous treatment at therapeutic doses in the absence of response in individuals with CKD;
- Use beyond 8 weeks of continuous treatment at therapeutic doses in the absence of response in individuals with myelodysplastic syndrome (MDS);

- Use beyond 8 weeks of continuous treatment at therapeutic doses in the absence of response or if transfusions are still required in individuals with metastatic, non-myeloid cancer being treated with myelosuppressive chemotherapy agents known to produce anemia;
- Continued use beyond 6 weeks after therapy with myelosuppressive chemotherapy known to produce anemia is completed;
- As a treatment in the presence of sudden loss of response with severe anemia and low reticulocyte count;
- To treat anemia in individuals with cancer receiving myelosuppressive chemotherapy in whom the anemia can be managed by transfusion.

## Step/Alternative Therapies:

| Preferred Product(s) [No PA Required] | Non-Preferred Product(s) [PA Required] |
|---|---|
| epoetin alfa-epbx, biosimilar, (Retacrit) [Q5105 or Q5106] | epoetin alfa (EPOGEN) |
| | epoetin alfa (PROCRIT) |

**Initial authorization for approved indications is up to 12 weeks.**

**Continuation requests may be approved if there is confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of the disease. Clinical documentation provided must be from within the most recent 12 months.**

**Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.**

**U.S. Food and Drug Administration:**
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage.

Erythropoietin is a glycoprotein which stimulates red blood cell production. Dosing and continued therapy dependent on response. Epogen® and Procrit® are indicated for:

- Anemia Due to Chronic Kidney Disease
- Anemia Due to Zidovudine in Patients with HIV-infection
- Anemia Due to Chemotherapy in Patients With Cancer
- Reduction of Allogeneic Red Blood Cell Transfusions in Patients Undergoing Elective, Noncardiac, Nonvascular Surgery

**References**:

*EPOGEN® (epoetin alfa) label*. (2017, September). Accessdata.fda.gov. Retrieved April 22, 2022, from https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/103234s5363s5366lbl.pdf
National Comprehensive Cancer Network, Inc. (Copyright © National Comprehensive Cancer Network, Inc). *NCCN Guidelines: Treatment by Cancer Type*. NCCN Clinical Practice Guidelines in Oncology. Retrieved April 22, 2022, from https://www.nccn.org/guidelines/category_1

*PROCRIT®*. (2018, July). Janssen Labels. Retrieved April 22, 2022, from https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/PROCRIT-pi.pdf
*PROCRIT®(epoetin alfa) label*. (2008, November 19). Accessdata.fda.gov. Retrieved April 22, 2022, from https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/103234s5196pi.pdf

**Criteria History/ Revision Information**:

| Date | Summary of Changes |
|---|---|
| April 2022 | Criteria for use summary developed by Ascension Medical Specialty Prior Authorization Team |
| May 2022 | Criteria for use summary approved by Ascension Therapeutic Affinity Group |

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team or email your questions to smarthealthspecialty@ascension.org.