blue california
Promise Health Plan

epoetin alfa

Medical Benefit Drug Policy

For oncology-related indications, coverage will be made based on medical necessity. Medical necessity determinations are made based on U.S. Food and Drug Administration (FDA) labeling, peer-reviewed medical literature, Medi-Cal coverage guidelines, and Centers for Medicare & Medicaid Services (CMS) approved compendia support (i.e., Clinical Pharmacology, National Comprehensive Cancer Network® (NCCN), American Hospital Formulary Service Drug Information, Thomson Micromedex DrugDex,® and Lexicomp®).

epoetin alfa (Procrit, Epogen)
epoetin alfa-epbx (Retacrit)

Place of Service
Home Infusion Administration
Hospital Administration
Infusion Center Administration
Office Administration
Outpatient Facility Administration
Self-Administration - *May be provided by the Pharmacy Benefit*

Drug Details

USP Category: BLOOD PRODUCTS AND MODIFIERS
Mechanism of Action: erythropoiesis-stimulating agent (ESA)
HCPCS:
J0885:Injection, epoetin alfa, (for non-esrd use), 1000 units
Q5106:Injection, epoetin alfa-epbx, biosimilar, (retacrit) (for non-esrd use), 1000 units
How Supplied:

- 2,000 Units/mL, 3,000 Units/mL, 4,000 Units/mL, 10,000 Units/mL, and 40,000 Units/mL (single-dose vials)
- 20,000 Units/2 mL (10,000 Units/mL) and 20,000 Units/mL (multiple-dose vials)

Condition(s) listed in policy *(see coverage criteria for details)*

- Anemia Due to Chronic Kidney Disease (CKD)
- Anemia Secondary to Zidovudine Therapy in HIV-Infected Patients
- Pre-Operative Prevention in Anemic Patients

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the California Code of Regulations (CCR), Title 22, Section 51303 and 51313 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

Retacrit is the BSC preferred erythropoiesis stimulating agent (ESA). For all covered indications, treatment failure, intolerance or contraindication to Retacrit (epoetin alfa-epbx) is required for members newly initiating ESA therapy.

Coverage Criteria
The following condition(s) require Prior Authorization/Preservice.

Anemia Due to Chronic Kidney Disease (CKD)
Meets medical necessity if all the following are met:
Initial:

1. For request for Procrit or Epogen: Intolerance or contraindication to Retacrit not expected of requested product
2. Hgb < 10 g/dL
3. Both Primary and Secondary ICD-10 codes (listed below) must be met

Reauthorization:
1. Hgb ≤ 11 g/dL

Covered Doses:
Initial: 100 units/kg given subcutaneously or intravenously 3 times per week
Maintenance: Individualize dosing to target a hemoglobin level of greater than 11 g/dL

Coverage Period:
yearly

ICD-10:
Primary: D63.1 (Anemia in ESRD), Secondary: N18.1-N18.9 (CRF)

Anemia Secondary to Zidovudine Therapy in HIV-Infected Patients
Meets medical necessity if all the following are met:
1. For request for Procrit or Epogen: Intolerance or contraindication to Retacrit not expected of requested product
2. On zidovudine therapy for HIV
3. Hgb < 10 g/dL
4. Both Primary and Secondary ICD-10 codes must be met

Covered Doses:

900 units/kg given subcutaneously or intravenously weekly

Coverage Period:
yearly

ICD-10:
Primary: D61.1 (drug-induced aplastic anemia), Secondary: B20 (HIV disease)

Pre-Operative Prevention in Anemic Patients
Meets medical necessity if all the following are met:

1. For request for Procrit or Epogen: intolerance or contraindication to Retacrit not expected with requested product
2. Hgb ≤ 13 g/dL
3. Patient is scheduled to undergo elective, non-cardiac, or non-vascular surgery
4. Patient is at high risk for perioperative transfusion with significant, anticipated blood loss (2 units of blood or more), and patient is not a candidate for blood transfusion

Covered Doses:
600 units/kg given subcutaneously or intravenously weekly for 4 doses or 300 units/kg given subcutaneously or intravenously daily for 15 days

Coverage Period:
For one surgery:

- 15-day regimen:given 10 days before surgery, on day of surgery, and 4 days after surgery
- 4-dose regimen: given once weekly at 21, 14, and 7 days prior to surgery and on day of surgery

ICD-10:
D64.9

References

1. AHFS. Available by subscription at http://www.lexi.com
2. DrugDex. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
3. Epogen (epoetin alfa) [prescribing information]. Thousand Oaks, CA: Amgen; December 2024.
4. Procrit (epoetin alfa) [prescribing information]. Horsham, PA: Janssen; April 2024.
5. Retacrit ((epoetin alfa-eobx) [prescribing information]. Pfizer Inc., Lake Forest, IL. 6.2024
6. National Comprehensive Cancer Network. Hematopoietic Growth Factors (Version 1.2025). Available at http://www.nccn.org.

7. National Comprehensive Cancer Network. Myelodysplastic Syndromes (Version 2.2025). Available at http://www.nccn.org.
8. National Comprehensive Cancer Network. Myeloproliferative Neoplasms (Version 2.2025). Available at http://www.nccn.org.

Review History

Date of Last Annual Review: 3Q2025
Changes from previous policy version:

- For oncology-related indications, coverage will be made based on medical necessity

Blue Shield of California Medication Policy to Determine Medical Necessity Reviewed by P&T Committee