Epoetin alfa (Procrit®, Epogen®) **Epoetin alfa-epbx (Retacrit™)**	**Place of Service** **Hospital Administration** **Office Administration** **Home Infusion Administration** **Outpatient Facility Administration** **Infusion Center Administration** **Self-Administration** **HCPCS** Procrit/Epogen: **J0885** per 1000 units (non-ESRD use) **Q4081** per 100 units (ESRD use on dialysis) Retacrit: **Q5105** per 100 units (ESRD on dialysis) **Q5106** per 1000 units (non-ESRD use)

Conditions listed in policy *(see criteria for details)*:

- Anemia due to chronic renal failure
- Anemia in patients with cancer who are undergoing palliative treatment
- Anemia of rheumatoid arthritis
- Anemia secondary to myelosuppressive chemotherapy in patients with cancer
- Anemia secondary to ribavirin therapy in hepatitis C patients
- Anemia secondary to zidovudine therapy in HIV-infected patients
- Myelodysplastic syndromes (MDS)
- Myelofibrosis-associated anemia
- Preoperative use for the anemic patient

AHFS therapeutic class: Hematopoietic Agent

Mechanism of action: Erythropoietin (EPO) is a glycoprotein hematopoietic growth factor. EPO is synthesized by the renal tubules in response to change in blood oxygen concentration. In anemic patients, the low blood oxygen concentration induces the production of EPO, which then acts on the erythroid cell in the bone marrow to stimulate hematopoiesis. Epoetin alfa is manufactured by recombinant DNA technology and has the same biological effects as endogenous erythropoietin.

(1) Special Instructions and Pertinent Information

This drug is managed under the outpatient Pharmacy Benefit for self-administration. Please contact the member's Pharmacy Benefit for information on how to obtain this drug.

To submit a request to the Medical Benefit, please submit clinical information for prior authorization review and include medical rationale why the patient cannot self-administer this drug in the home.

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.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for epoetin alfa must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Anemia due to chronic renal failure (CRF)

1. For request for Procrit or Epogen: Intolerance or contraindication to Retacrit not expected of requested product, **AND**
2. Hgb < 10 g/dL or HCT < 30%**, AND**
3. Both Primary and Secondary ICD-10 codes (listed below) must be met

Covered Doses
Up to 300 units/kg SC/IV weekly

Coverage Period
Initial: 1 year

Reauthorization: Cover yearly if Hgb ≤ 11 g/dL

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

Anemia in patients with cancer who are undergoing palliative treatment

1. For request for Procrit or Epogen: Intolerance or contraindication to Retacrit not expected of requested product, **AND**
2. Physician attestation that the patient is undergoing palliative treatment, **AND**
3. Hgb < 10 gm/dl

Covered Doses
Up to 900 units/kg SC weekly or up to 60,000 units SC weekly

Coverage Period
Indefinite

ICD-10:
D63.0, D63.1, D64.81, D64.9, Z51.11, Z51.89

Anemia secondary to myelosuppressive chemotherapy in patients with cancer

1. For request for Procrit or Epogen: Intolerance or contraindication to Retacrit not expected of requested product, **AND**
2. Patient is currently on chemotherapy or has completed their last dose of chemotherapy within the past 8 weeks, or patient has multiple myeloma and is on Revlimid (lenalidomide) therapy, **AND**
3. Hgb < 10 g/dL

Covered Doses

- Administered weekly: Up to 900 units/kg IV/SC per week
- Administered every 2 weeks: Up to 80,000 units IV/SC per week
- Administered every 3 weeks: Up to 120,000 units IV/SC per week

Coverage Period
Indefinite

ICD-10: D63.0, D64.81, Z51.11

Anemia secondary to zidovudine therapy in HIV-infected patients

1. For request for Procrit or Epogen: Intolerance or contraindication to Retacrit not expected of requested product, **AND**
2. On Zidovudine therapy for HIV, **AND**
3. Hgb < 10 g/dL, **AND**
4. Both Primary and Secondary ICD-10 codes must be met

Covered Doses
Up to 900 units/kg SC/IV week

Coverage Period
Indefinite

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

Myelodysplastic syndromes (MDS)

1. For request for Procrit or Epogen: Intolerance or contraindication to Retacrit not expected of requested product, **AND**
2. Hgb < 10 g/dL, **AND**
3. Baseline serum EPO ≤ 500 mU/ml drawn prior to Procrit/Epogen therapy

Covered Doses
Up to 120,000 units IV/SC per week

Coverage Period
Indefinite

ICD-10:
D46.0, D46.1, D46.2, D46.21, D46.22, D46.4, D46.A, D46.B, D46.C, D46.9, D46.Z

Myelofibrosis-associated anemia

1. For request for Procrit or Epogen: intolerance or contraindication to Retacrit not expected with requested product, **AND**
2. Hgb < 10 g/dL, **AND**
3. Baseline serum EPO < 500 mU/ml drawn prior to epoetin alfa therapy

Covered Doses
Up to 180,000 units IV/SC per week

Coverage Period
Indefinite

ICD-10:
C94.40-C94.42, D47.4, D75.81

Pre-operative prevention in anemic patients

1. For request for Procrit or Epogen: intolerance or contraindication to Retacrit not expected with requested product, **AND**
2. Hgb ≤ 13 g/dL, **AND**
3. Patient is scheduled to undergo elective, non-cardiac, or non-vascular surgery, **AND**
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
Up to 600 units/kg IV/SC per week for 4 doses, or up to 300 units/kg IV/SC per day for 15 days

Coverage Period
For one surgery: Typically given 10 days before surgery, on day of surgery, and 4 days after surgery (15 days total)

ICD-10:
D64.9 (Anemia, unspecified)

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Epoetin alfa must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Blue Shield's research indicates there is inadequate clinical evidence to support off-label use of this drug for the following conditions (Health and Safety Code 1367.21):

- Treatment is not covered when Hgb > 12 g/dL or HCT > 36% for all indications
- (280.0) Iron deficiency anemias; secondary to blood loss (chronic)
- (280.9) Iron deficiency anemia, unspecified
- (281.9) Unspecified deficiency anemia
- (283.0) Autoimmune hemolytic anemias
- (284.9) Aplastic anemia, unspecified
- (285.9) Anemia, unspecified (except for EPO for preoperative use)
- (288.0) Agranulocytosis
- (289.9) Unspecified diseases of blood and blood forming organs
- (451.9) Phlebitis and thrombophlebitis of deep vessels of lower extremities; other
- (V59.01) Donors; blood; whole blood
- (205.00-205.91) Myeloid leukemia
- (206.00-206.91) Monocytic leukemia
- (207.00-208.91) Other specified and unspecified leukemias
- (Z52.01-Z52.018) Future Autologous Transfusion

Anemias due to:

- Athletic performance management
- Beta-thalassemia
- Blood transfusion reduction
- Cancer radiotherapy
- Cofactor deficiencies
- Congestive heart failure
- Folate deficiency anemia
- Hemolysis
- Hemorrhage
- Insulin resistance
- Most patients with GI bleeding
- Nutritional deficiencies
- Porphyria
- Postpartum
- Prematurity
- Puerperium
- Sexual dysfunction
- Sickle-cell anemia
- Radiation
- Refractory anemia such as thalassemia or sickle cell disease
- Transfusional iron overload
- Untreated underlying infections

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

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)

Key:

Hgb = hemoglobin level, measured in grams per deciliter (g/dL)
HCT = hematocrit level, reported in %
EPO = Erythropoietin level, reported in microunits per milliliter (mU/ml)

Concurrent iron supplementation is recommended.

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- Epogen® (epoetin alfa) Prescribing Information. Thousand Oaks, CA: Amgen, Inc., 7/2018.
- National Comprehensive Cancer Network. Hematopoietic Growth Factors (Version 1.2022). Available at http://www.nccn.com.
- National Comprehensive Cancer Network. Myelodysplastic Syndromes (Version 3.2022). Available at http://www.nccn.com.
- National Comprehensive Cancer Network. Myeloproliferative Neoplasms (Version 2.2022). Available at http://www.nccn.org.
- Procrit® (epoetin alfa) Prescribing Information. Thousand Oaks, CA: Amgen, Inc., 7/2018.
- Rizzo JD, Brouwers M, Hurley P et al. American Society of Clinical Oncology/American Society of Hematology clinical practice guideline update on the use of epoetin and darbepoetin in adult patients with cancer. J Clin Oncol. 2010;28(33):4996-5010.
- Tsiara SN, Chaidos A, Bourantas LK et al. Recombinant human erythropoietin for the treatment of anemia in patients with chronic myelofibrosis. Acta Haematol 2007; 117(3): 156-61.

(7) Policy Update

Date of last review: 3Q2022
Date of next review: 3Q2023
Changes from previous policy version:

- No clinical change to policy following routine annual review.

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee