Epoetin Alfa Products for Dialysis (Epogen®, Procrit®, Retacrit®)

NDC CODE(S)

55513-0126-XX EPOGEN 2000UNIT/ML Solution (AMGEN)
55513-0144-XX EPOGEN 10000UNIT/ML Solution (AMGEN)
55513-0148-XX EPOGEN 4000UNIT/ML Solution (AMGEN)
55513-0267-XX EPOGEN 3000UNIT/ML Solution (AMGEN)
55513-0283-XX EPOGEN 10000UNIT/ML Solution (AMGEN)
55513-0478-XX EPOGEN 20000UNIT/ML Solution (AMGEN)
59676-0302-XX PROCRIT 2000UNIT/ML Solution (JANSSEN PRODUCTS)
59676-0303-XX PROCRIT 3000UNIT/ML Solution (JANSSEN PRODUCTS)
59676-0304-XX PROCRIT 4000UNIT/ML Solution (JANSSEN PRODUCTS)
59676-0310-XX PROCRIT 10000UNIT/ML Solution (JANSSEN PRODUCTS)
59676-0312-XX PROCRIT 10000UNIT/ML Solution (JANSSEN PRODUCTS)
59676-0320-XX PROCRIT 20000UNIT/ML Solution (JANSSEN PRODUCTS)
59676-0340-XX PROCRIT 40000UNIT/ML Solution (JANSSEN PRODUCTS)
00069-1305-XX RETACRIT 2000UNIT/ML Solution (PFIZER U.S.)
00069-1306-XX RETACRIT 3000UNIT/ML Solution (PFIZER U.S.)
00069-1307-XX RETACRIT 4000UNIT/ML Solution (PFIZER U.S.)
00069-1308-XX RETACRIT 10000UNIT/ML Solution (PFIZER U.S.)
00069-1309-XX RETACRIT 40000UNIT/ML Solution (PFIZER U.S.)
00069-1311-XX RETACRIT 20000UNIT/ML Solution (PFIZER U.S.)
00069-1318-XX RETACRIT 10000U/ML Solution (PFIZER U.S.)
59353-0002-XX RETACRIT 2000UNIT/ML Solution (VIFOR)
59353-0003-XX RETACRIT 3000 UNIT/ML Solution (VIFOR)
59353-0004-XX RETACRIT 4000UNIT/ML Solution (VIFOR)
59353-0010-XX RETACRIT 10000UNIT/ML Solution (VIFOR)
59353-0120-XX RETACRIT 20000UN/ML Solution (VIFOR)
59353-0220-XX RETACRIT 10000UN/ML Solution (VIFOR)
59353-0002-XX RETACRIT 2000UNIT/ML Solution (VIFOR)
59353-0003-XX RETACRIT 3000 UNIT/ML Solution (VIFOR)

DESCRIPTION

Erythropoietin is a glycoprotein produced in the kidneys responsible for the stimulation of erythropoiesis. It increases the reticulocyte count to initiate red blood cell production and is referred to as an erythropoietin-stimulating agent or an ESA.

Manufactured by recombinant DNA technology, epoetin alfa (Epogen®/Procrit®) is a 165-amino acid manufactured in the identical amino acid sequence of isolated natural erythropoietin. Like the endogenous hormone, it stimulates increased reticulocyte production followed by red blood cells in individuals with functioning erythropoiesis.

Epoetin alfa-epbx (Retacrit®) is biosimilar to epoetin alfa. It contains the identical amino acid sequence of isolated natural erythropoietin and is also a 165-amino acid erythropoiesis-stimulating glycoprotein manufactured by recombinant DNA technology. It's use is interchangeable with epoetin alfa products.

This policy addresses the use of Epoetin Alfa Products in the treatment of Dialysis Patients.

POLICY

- Epoetin Alfa products for the treatment of anemia due to CKD-dialysis is considered ***medically necessary*** if the medical appropriateness criteria are met. **(See Medical Appropriateness below.)**
- Epoetin Alfa products for the treatment of other conditions/diseases is considered ***investigational.***

MEDICAL APPROPRIATENESS

INITIAL APPROVAL CRITERIA

- Patient is at least 1 month of age; **AND**

Universal Criteria

- Lab values are obtained within 30 days of the date of administration (unless otherwise indicated); **AND**
- Patient has adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20% (measured within the previous 3 months for renewal)*; **AND**
- Other causes of anemia (e.g. hemolysis, bleeding, vitamin deficiency, etc.) have been ruled out; **AND**
- Patient does not have uncontrolled hypertension; **AND**

Anemia Secondary to Chronic Kidney Disease (dialysis patients)

- Initiation of therapy Hemoglobin (Hb) < 10 g/dL and/or Hematocrit (Hct) < 30%

RENEWAL CRITERIA

- Patient continues to meet universal and other indication-specific relevant criteria identified in the Initial Approval Criteria; **AND**
- Previous dose was administered withing the past 60 days; **AND**
- Anemia response compared to pretreatment baseline; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe cardiovascular events (stroke, myocardial infarction, congestive heart failure, thromboembolism, etc.), uncontrolled hypertension), increased risk of tumor progression/ or recurrence in patients with cancer, seizures, pure red cell aplasia, serious allergic reactions (anaphylaxis, angioedema, bronchospasm, etc.), severe cutaneous reactions (erythema multiforme, Stevens-Johnson Syndrome [SJS]/Toxic Epidermal Necrolysis [TEN], etc.), "gasping syndrome" (central nervous system depression, metabolic acidosis, gasping respirations) due to benzyl alcohol preservative, etc.; **AND**

Anemia Secondary to Chronic Kidney Disease:

- **Pediatric patients:** Hemoglobin (Hb) < 12 g/dL and/or Hematocrit (Hct) < 36%
- **Adults:** Hemoglobin (Hb) < 11 g/dL and/or Hematocrit (Hct) < 33%

* *Intravenous iron supplementation may be taken into account when evaluating iron status*

- Functional iron deficiency (i.e., adequate iron stores with an insufficient supply of available iron) may occur in patients with chronic diseases, cancer, and/or in those currently receiving ESAs.
- Iron is not generally recommended in anemic patients with a Ferritin >500 ng/mL
- Anemic patients with a Ferritin ≤500 ng/mL AND TSAT <50% may derive benefit from IV iron therapy in conjunction with ESA

DOSAGE/ADMINISTRATION

INDICATION	DOSE
Anemia due to CKD - Dialysis§	• Adults: 50-100 units/kg intravenously or subcutaneously three times weekly • Pediatric patients: 50 units/kg intravenously or subcutaneously three times weekly
§ ▫ Dose increases of 25% can be considered if after 4 weeks of initial therapy the hemoglobin has increased less than 1 g/dL and the current hemoglobin level is less than the indication specific level noted above. ▫ Dose decreases of 25% or more can be considered if the hemoglobin rises rapidly by more than 1 g/dL in any 2-week period. ▫ Dose and frequency requested are the minimum necessary for the patient to avoid RBC transfusions. ▫ Avoid frequent dose adjustments. Do not increase the dose more frequently than once every 4 weeks; decreases can occur more frequently. ▫ If patients fail to respond over a 12-week dose escalation period, further dose increases are unlikely to improve response and discontinuation of therapy should be considered.	

LENGTH OF AUTHORIZATION

Coverage will be provided for 12 months and may be renewed.

DOSING LIMITS

Max Units (per dose and over time) [HCPCS Unit]:

- 400 billable units every 7 days

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the Medical Policy and a health plan, the express terms of the health plan will govern.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

SOURCES

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11. Thadhani R, Guilatco R, Hymes J, et al. Switching from Epoetin Alfa (Epogen®) to Epoetin Alfa-Epbx (Retacrit™) Using a Specified Dosing Algorithm: A Randomized, Non-Inferiority Study in Adults on Hemodialysis. Am J Nephrol. 2018;48(3):214-224.
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13. US Food and Drug Administration. FDA briefing document. Oncologic Drugs Advisory Committee Meeting. BLA 125545: Epoetin Hospira, a proposed biosimilar to Epogen/Procrit (epoetin alfa). Hospira Inc., a Pfizer Company. May 25, 2017.
14. Mikhail A, Brown C, Williams JA, et al. Renal association clinical practice guideline on Anaemia of Chronic Kidney Disease. BMC Nephrol. 2017 Nov 30;18(1):345. doi: 10.1186/s12882-017-0688-1.
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EFFECTIVE DATE 8/31/2021

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