Clinical Policy: Epoetin Alfa (Epogen, Procrit), Epoetin Alfa-epbx (Retacrit)

Reference Number: IN.CP.PHAR.237
Effective Date: 01.01.2022
Last Review Date: 12.21
Line of Business: Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Epoetin alfa (Epogen®, Procrit®) and its biosimilar, epoetin alfa-epbx (Retacrit™), are erythropoiesis-stimulating agents (ESAs).

FDA Approved Indication(s)

Epogen, Procrit, and Retacrit are indicated for:

- Treatment of anemia due to:
  - Chronic kidney disease (CKD) in patients on dialysis and not on dialysis.
  - Zidovudine in patients with HIV-infection.
  - The effects of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy.
- Reduction of allogeneic red blood cell (RBC) transfusions in patients undergoing elective, noncardiac, nonvascular surgery.

Limitation(s) of use:

- Epogen, Procrit, and Retacrit have not been shown to improve quality of life, fatigue, or patient well-being.
- Epogen, Procrit, and Retacrit are not indicated for use:
  - In patients with cancer receiving hormonal agents, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy.
  - In patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure.
  - In patients with cancer receiving myelosuppressive chemotherapy in whom the anemia can be managed by transfusion.
  - In patients scheduled for surgery who are willing to donate autologous blood.
  - In patients undergoing cardiac or vascular surgery.
  - As a substitute for RBC transfusions in patients who require immediate correction of anemia.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Initial Approval Criteria

A. Must meet one of the following:
1. Anemia in members with one of the following:

a. Chronic kidney disease
b. Congestive heart failure
c. Hepatitis C for members receiving ribavirin with interferon alfa or ribavirin with peginterferon alfa
d. HIV-infected members receiving zidovudine
e. Multiple myeloma
f. Myelodysplastic syndrome (MDS)
g. Myelofibrosis
h. Neoplastic disease not associated with chemotherapy
i. Rheumatoid arthritis
j. Transfusion-dependent beta thalassemia

2. Chemotherapy-induced anemia in members with nonmyeloid malignancies/neoplastic disease and at least 2 additional months of chemotherapy is planned
3. Chronic anemia in neoplastic disease not associated with chemotherapy
4. Reduction in allogenic blood transfusions in anemic surgical patients (e.g., elective noncardiac, nonvascular surgeries) at high risk for perioperative blood loss
5. Anemia due to trauma or postsurgical event, transfusion refusal (e.g., Jehovah's Witness)
6. Anemia associated with radiation therapy
7. Post-partum anemia (during the puerperium)
8. Anemia of prematurity
9. Blood unit collection in preparation for autotransfusion
10. Iron overload transfusion
11. If Epogen or Procrit is requested, failure of Retacrit, unless contraindicated or clinically significant adverse effects are experienced.

Approval duration:
Medicaid– 6 months

B. Other diagnoses/indications

1. If Epogen or Procrit is requested, failure of Retacrit, unless contraindicated or clinically significant adverse effects are experienced;
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized):CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Anemia due to Chronic Kidney Disease (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
2. Member is responding positively to therapy;
3. If Epogen or Procrit is requested, failure of Retacrit, unless contraindicated or clinically significant adverse effects are experienced;

Approval Duration:
Medicaid/HIM – 6 months (*see Appendix D for dose rounding guidelines*)

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III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

CKD: chronic kidney disease
ESA: erythropoiesis-stimulating agent
FDA: Food and Drug Administration
HIV: human immunodeficiency virus
RBC: red blood cell

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Uncontrolled hypertension
  - Pure red cell aplasia (PRCA) that begins after treatment with erythropoietin protein drugs
  - Allergic reactions
  - Use of the multiple-dose vials containing benzyl alcohol in neonates, infants, pregnant women, and lactating women
- Boxed warning(s): ESAs increase the risk of death, myocardial infarction, stroke, venous thromboembolism, thrombosis of vascular access and tumor progression or recurrence

IV. References

1. Epogen Prescribing Information. Thousand Oaks, CA: Amgen Inc.; July 2018. Available at http://www.epogen.com/. Accessed February 23, 2021.
2. Procrit Prescribing Information. Thousand Oaks, CA: Amgen Inc.; July 2018. Available at http://www.procrit.com/. Accessed February 23, 2021.
3. Bohlius J, Bohlke K, Castelli R, et al. American Society of Hematology/American Society of Clinical Oncology clinical practice guideline update: Management of Cancer-Associated Anemia With Erythropoiesis-Stimulating Agents. J Clin Oncol 37:1336-1351. Available at: https://ascopubs.org/doi/pdf/10.1200/JCO.18.02142. Accessed February 23, 2021.
4. Mancino P, Falasca K, Ucciferri C, Pizzigallo E, Vecchiet J. Use of Hematopoietic Growth Factor in the Management of Hematological Side Effects Associated to Antiviral Treatment for Hcv Hepatitis. Mediterranean Journal of Hematology and Infectious Diseases. 2010;2(1):e2010003. doi:10.4084/MJHID.2010.003.
5. Afdhal NH, Dieterich DT, et al. Epoetin alfa maintains ribavirin dose in HCV-infected patients: a prospective, double-blind, randomized controlled study. Gastroenterology. 2004 May;126(5):1302-11.
6. Epoetin alfa. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at NCCN.org. Accessed February 23, 2021.

7. Myelodysplastic Syndromes (Version 3.2021). In: National Comprehensive Cancer Network Guidelines. Available at www.nccn.org. Accessed February 23, 2021.
8. Myeloproliferative Neoplasms (Version 1.2020). In National Comprehensive Cancer Network Guidelines. Available at www.nccn.org. Accessed February 23, 2021.
9. Hematopoietic Growth Factors (Version 1.2021). In National Comprehensive Cancer Network Guidelines. Available at www.nccn.org. Accessed February 23, 2021.
10. Epoetin Alfa Drug Monograph. Clinical Pharmacology. Accessed February 23, 2021. http://www.clinicalpharmacology-ip.com.
11. DRUGDEX® System [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed February 23, 2021.
12. Retacrit Prescribing Information. Lake Forest, IL: Hospira, Inc., June 2020. Available at https://www.pfizerpro.com/product/retacrit/hcp. Accessed February 23, 2021.

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
Q4081	Injection, epoetin alfa, 100 units (for ESRD on dialysis)
J0885	Injection, epoetin alfa, (for non-ESRD use), 1000 units
Q5105	Injection, epoetin alfa, biosimilar, (Retacrit) (for ESRD on dialysis), 100 units
Q5106	Injection, epoetin alfa, biosimilar, (Retacrit) (for non-ESRD use), 1000 units

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Created to meet requirements of IN Medicaid Moratorium	12.2022	01.2022