BlueCross BlueShield
Federal Employee Program

Epogen, Procrit (epoetin alfa), **Retacrit** (epoetin alfa – epbx)

Preferred product: Retacrit
Epogen is neither preferred nor non-preferred

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Epogen, Procrit and Retacrit are erythropoiesis-stimulating agents (ESAs) that bind to progenitor stem cells and stimulates the production and differentiation of red blood cells (RBC). Epogen, Procrit and Retacrit stimulate erythropoiesis by the same mechanism as endogenous erythropoietin. Epogen, Procrit and Retacrit increase the reticulocyte count within 10 days of initiation, followed by increases in the RBC count, hemoglobin, and hematocrit, usually within 2 to 6 weeks. The rate of hemoglobin increase varies among patients and is dependent upon the dose of Epogen, Procrit, or Retacrit being administered. Retacrit is a biosimilar to Epogen. (1-3).

Regulatory Status

FDA-approved indications: Epogen, Procrit and Retacrit are erythropoiesis-stimulating agents (ESA) indicated for: (1-3)

1. Treatment of anemia due to
    a. Chronic Kidney Disease (CKD) in patients on dialysis and not on dialysis.
    b. Zidovudine in HIV-infected patients.
    c. The effects of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy.
1. Reduction of allogeneic RBC transfusions in patients undergoing elective, non-cardiac, nonvascular surgery

<u>Limitations of Use</u>: (1-3)

Epogen, Procrit and Retacrit have not been shown to improve quality of life, fatigue, or patient wellbeing.

Epogen, Procrit and Retacrit are not indicated for use:

1. In patients with cancer receiving hormonal agents, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy.
2. In patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure.

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3. In patients with cancer receiving myelosuppressive chemotherapy in whom the anemia can be managed by transfusion
4. In patients scheduled for surgery who are willing to donate autologous blood.
5. In patients undergoing cardiac or vascular surgery.
6. As a substitute for RBC transfusions in patients who require immediate correction of anemia.

Off-Label Uses: (4-8)

1. Symptomatic anemia in patients with myelodysplastic syndromes (MDS)
2. Anemia in rheumatoid arthritis
3. Anemia due to hepatitis C treatment with ribavirin in combination with either interferon alfa or peginterferon alfa
4. Allogeneic bone marrow transplantation

Epogen, Procrit and Retacrit carry warnings citing the increased risk of myocardial infarction, stroke, venous thromboembolism, thrombosis of vascular access, and tumor progression or recurrence (1-3).

Myelodysplastic syndromes (MDS) encompass a series of hematological conditions characterized by chronic cytopenias, including anemia, accompanied by abnormal cellular maturation. As a result, patients with MDS are at risk for symptomatic anemia. At least 80 percent of patients are anemic at the time of diagnosis, while about 50 percent have a hemoglobin level less than 10 g/dL. The use of epoetin alfa for the treatment of symptomatic anemia in patients with MDS is an unlabeled or investigational use according to the FDA. However, their use in MDS is supported by the American Society of Hematology (ASH), the American Society of Clinical Oncology (ASCO), and the National Comprehensive Cancer Network (NCCN) (4-5).

Anemia associated with Hepatitis C therapy is a frequent cause of dose reduction or discontinuation of therapy. Clinical recommendation is to reduce the dosage if anemia developed. This reduction increases the likelihood of treatment failure. Addition of an ESA agent allows the optimal probability of treatment success (6).

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The National Kidney Foundation Kidney Disease Outcomes Quality Initiative (NKF KDOQI) provides evidence based clinical guidelines for improving treatment and outcomes in patients with kidney disease. Their recommendations for transferrin saturation, serum ferritin and hemoglobin levels establish a standard of care and are incorporated into this criterion (7). Treatment of anemia associated with rheumatoid arthritis has been shown to reduce disease activity (8).

Several sources, such as the Renal Association, recommend therapy with erythropoietin stimulating agents when the hemoglobin level is less than 11 g/dL in patients not on dialysis (9-11).

Summary

Epogen, Procrit, and Retacrit are erythropoiesis-stimulating agents (ESAs) that bind to progenitor stem cells and stimulates the production and differentiation of red blood cells (RBC). Epogen, Procrit, and Retacrit stimulate erythropoiesis by the same mechanism as endogenous erythropoietin (1-3).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Epogen, Procrit, and Retacrit while maintaining optimal therapeutic outcomes.

References

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