Effective Date: 1/2019
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NON-ONCOLOGY POLICY
EPOGEN, PROCRIT, RETACRIT (epoetin alfa)

For oncology indications, please refer to NHPRI Erythropoiesis Stimulating Agents (ESA) and Biosimilar Oncology Policy

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications
1. Epoetin alfa is indicated for the treatment of anemia due to chronic kidney disease (CKD), including patients on dialysis and not on dialysis to decrease the need for red blood cell (RBC) transfusion.
2. Epoetin alfa is indicated for the treatment of anemia due to zidovudine administered at ≤ 4200 mg/week in HIV-infected patients with endogenous serum erythropoietin levels of ≤ 500 mUnits/mL.
3. Epoetin alfa is indicated to reduce the need for allogeneic RBC transfusions among patients with perioperative hemoglobin > 10 to ≤ 13 g/dL who are at high risk for perioperative blood loss from elective, noncardiac, nonvascular surgery. Epoetin alfa is not indicated for patients who are willing to donate autologous blood preoperatively.

Limitations of Use:
1. Epoetin alfa has not been shown to improve quality of life, fatigue, or patient well-being.
2. Epoetin alfa is 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 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.

B. Compendial Uses
1. Anemia in congestive heart failure
2. Anemia in rheumatoid arthritis
3. Anemia due to hepatitis C treatment with ribavirin in combination with either interferon alfa or peginterferon alfa
4. Anemia in patients whose religious beliefs forbid blood transfusions

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL – For Epogen and Procrit requests, the member must have tried and failed or have a contraindication to Retacrit.

Note: Requirements regarding pretreatment hemoglobin level exclude values due to a recent transfusion.

A. Anemia Due to CKD
Authorization of 12 weeks may be granted for members with pretreatment hemoglobin < 10 g/dL.

B. Reduction of Allogeneic Red Blood Cell Transfusion in Patients Undergoing Elective, Noncardiac, Nonvascular Surgery
Authorization of 12 weeks may be granted for members scheduled to have an elective, noncardiac, nonvascular surgery when the pretreatment hemoglobin is > 10 to ≤ 13 g/dL.

C. Anemia in Congestive Heart Failure (CHF)
Authorization of 12 weeks may be granted for members with pretreatment hemoglobin < 9 g/dL.

D. Anemia in Rheumatoid Arthritis (RA)
Authorization of 12 weeks may be granted for members with pretreatment hemoglobin < 10 g/dL.

E. Anemia Due to Hepatitis C Treatment
Authorization of 12 weeks may be granted for members with pretreatment hemoglobin < 10 g/dL who are receiving ribavirin in combination with either interferon alfa or peginterferon alfa.

F. Anemia Due to Zidovudine in HIV-infected Patients
Authorization of 12 weeks may be granted for members currently receiving zidovudine with pretreatment hemoglobin < 10 g/dL.

I. Anemia in Members Whose Religious Beliefs Forbid Blood Transfusions
Authorization of 12 weeks may be granted for members with pretreatment hemoglobin < 10 g/dL.

III. CONTINUATION OF THERAPY

Note: Requirements regarding current hemoglobin level exclude values due to a recent transfusion.

For all indications below: all members (including new members) requesting authorization for continuation of therapy after at least 12 weeks of ESA treatment must show a response with a rise in hemoglobin of ≥ 1 g/dL. Members who completed less than 12 weeks of ESA treatment and have not yet responded with a rise in hemoglobin of ≥ 1 g/dL may be granted authorization of up to 12 weeks to allow for sufficient time to demonstrate a response.

A. Anemia Due to CKD
Authorization of 12 weeks may be granted for continuation of therapy when the current hemoglobin is ≤ 12 g/dL.

B. Anemia in CHF, RA
Authorization of 12 weeks may be granted for continuation of treatment when the current hemoglobin is ≤ 12 g/dL.

C. Anemia Due to Hepatitis C Treatment
Authorization of 12 weeks may be granted for continuation of treatment when the member meets ALL of the following criteria:
1. The member is receiving ribavirin in combination with either interferon alfa or peginterferon alfa
2. The current hemoglobin is ≤ 12 g/dL.

D. Anemia Due to Zidovudine in HIV-infected Patients
Authorization of 12 weeks may be granted for continuation of therapy in members receiving zidovudine when the current hemoglobin is ≤ 12 g/dL.

E. Anemia in Members Whose Religious Beliefs Forbid Blood Transfusions
Authorization of 12 weeks may be granted for continuation of treatment when the current hemoglobin is ≤ 12 g/dL.

IV. REFERENCES

1. Epogen [package insert]. Thousand Oaks, CA: Amgen Inc.; July 2018.
2. Procrit [package insert]. Horsham, PA: Janssen Products.; May 2020.
3. Retacrit [package insert]. Lake Forest, IL: Hospira Inc.; June 2021.
4. Micromedex Solutions [database online]. Ann Arbor, MI: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. Accessed September 19, 2018.
5. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed September 19, 2018.
6. Kidney Disease: Improving Global Outcomes (KDIGO) Anemia Work Group. KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease. Kidney Int. 2012;Suppl 2:279-335.
7. National Kidney Foundation. KDOQI Clinical Practice Guideline and Clinical Practice Recommendations for Anemia in Chronic Kidney Disease: 2007 Update of Hemoglobin Target. http://www2.kidney.org/professionals/KDOQI/guidelines_anemiaUP/. Accessed September 19, 2018.
8. Qaseem A, Humphrey LL, Fitterman N, Starkey M, Shekelle P, for the Clinical Guidelines Committee of the American College of Physicians. Treatment of Anemia in Patients with Heart Disease: A Clinical Practice Guideline from the American College of Physicians. *Ann Intern Med.* 2013;159:770-779.