SPECIALTY GUIDELINE MANAGEMENT

EPOGEN, PROCRIT (epoetin alfa)

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 in patients with non-myeloid malignancies where anemia is due to the effect of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy.
3. 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.
4. 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:
- Epoetin alfa has not been shown to improve quality of life, fatigue, or patient well-being.
- 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 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. Symptomatic anemia in patients with myelodysplastic syndromes (MDS)
2. Anemia in congestive heart failure
3. Anemia in rheumatoid arthritis
4. Anemia due to hepatitis C treatment with ribavirin in combination with either interferon alfa or peginterferon alfa
5. Anemia in patients whose religious beliefs forbid blood transfusions

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

II. REQUIRED DOCUMENTATION

The following information is necessary to initiate the prior authorization review: Laboratory report of hemoglobin level (pretreatment if ESA naive, current if on ESA therapy) obtained within 30 days of request.
III. CRITERIA FOR INITIAL APPROVAL

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. Anemia Due to Myelosuppressive Chemotherapy
Authorization of 12 weeks may be granted for members with nonmyeloid malignancy who meet ALL of the following criteria:
1. Member is expected to receive at least two more months of chemotherapy
2. The intent of chemotherapy is non-curative
3. Pretreatment hemoglobin < 10 g/dL

C. Anemia Due to Zidovudine in HIV-infected Patients
Authorization of 12 weeks may be granted for HIV-infected members currently receiving ≤ 4200 mg/week of zidovudine who meet BOTH of the following criteria:
1. Pretreatment hemoglobin < 10 g/dL
2. Pretreatment serum erythropoietin level < 500 mU/mL

D. 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 who meet BOTH of the following criteria:
1. Pretreatment hemoglobin > 10 to ≤ 13 g/dL
2. Epoetin alfa is not being prescribed to facilitate pre-operative autologous blood donation

E. Anemia in MDS
Authorization of 12 weeks may be granted for members who meet ALL of the following criteria:
1. Member has symptomatic anemia
2. Pretreatment hemoglobin < 10 g/dL
3. Pretreatment serum erythropoietin level < 500 mU/mL

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

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

H. 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.

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.

IV. 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 \( \geq 1 \) 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 members on dialysis who meet ANY of the following criteria:
1. Current hemoglobin \( \leq 11 \) g/dL
2. Current hemoglobin \( > 11 \) to \( \leq 12 \) g/dL and prescriber will interrupt or decrease dosing to the lowest dose sufficient to reduce the need for RBC transfusions

Authorization of 12 weeks may be granted for members not on dialysis who meet ANY of the following criteria:
1. Current hemoglobin \( < 10 \) g/dL
2. Current hemoglobin \( > 10 \) to \( < 12 \) g/dL and prescriber will interrupt or decrease dosing to the lowest dose sufficient to reduce the need for RBC transfusions

B. Anemia Due to Myelosuppressive Chemotherapy
Authorization of 12 weeks may be granted for members with nonmyeloid malignancy who meet BOTH of the following criteria:
1. The intent of chemotherapy is non-curative
2. Current hemoglobin \( < 11 \) g/dL

C. Anemia Due to Zidovudine in HIV-infected Patients
Authorization of 12 weeks may be granted for HIV-infected members currently receiving \( \leq 4200 \) mg/week of zidovudine who meet ANY of the following criteria:
1. Current hemoglobin \( < 11 \) g/dL
2. Current hemoglobin \( > 11 \) to \( < 12 \) g/dL and prescriber will interrupt or decrease dosing to the lowest dose sufficient to reduce the need for RBC transfusions

D. Anemia in MDS
Authorization of 12 weeks may be granted for members who meet BOTH of the following criteria:
1. Member has symptomatic anemia
2. Member meets either of the following:
   a. Current hemoglobin \( \leq 11 \) g/dL
   b. Current hemoglobin \( > 11 \) to \( < 12 \) g/dL and prescriber will interrupt or decrease dosing to the lowest dose sufficient to reduce the need for RBC transfusions

E. Anemia in CHF, RA
Authorization of 12 weeks may be granted for members who meet ANY of the following criteria:
1. Current hemoglobin \( < 11 \) g/dL
2. Current hemoglobin \( > 11 \) to \( < 12 \) g/dL and prescriber will interrupt or decrease dosing to the lowest dose sufficient to reduce the need for RBC transfusions

F. Anemia Due to Hepatitis C Treatment
Authorization of 12 weeks may be granted for members who are receiving ribavirin in combination with either interferon alfa or peginterferon alfa and meet ANY of the following criteria:
1. Current hemoglobin \( \leq 11 \) g/dL
2. Current hemoglobin \( > 11 \) to \( \leq 12 \) g/dL and prescriber will interrupt or decrease dosing to the lowest dose sufficient to reduce the need for RBC transfusions

G. Anemia in members whose religious beliefs forbid blood transfusions
Authorization of 12 weeks may be granted for members who meet ANY of the following criteria:
1. Current hemoglobin \( < 11 \) g/dL
2. Current hemoglobin \( > 11 \) to \( < 12 \) g/dL and prescriber will interrupt or decrease dosing to the lowest dose sufficient to reduce the need for RBC transfusions
V. DOSAGE AND ADMINISTRATION
Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

VI. REFERENCES