Reference number(s)
1619-A

SPECIALTY GUIDELINE MANAGEMENT

EPOGEN, PROCRIT, RETACRIT (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 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 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.
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.

B. Compendial Uses
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. Anemia in patients whose religious beliefs forbid blood transfusions
5. Symptomatic anemia in patients with primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis
6. Cancer patients who are undergoing palliative treatment

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

Note: Requirements regarding pretreatment hemoglobin level exclude values due to a recent transfusion. All members must be assessed for iron deficiency anemia and have adequate iron stores (defined as a serum transferrin saturation [TSAT] level greater than or equal to 20% within the prior 3 months) or are receiving iron therapy before starting Epogen/Procrit/Retacrit. Members may not use Epogen/Procrit/Retacrit concomitantly with other erythropoiesis stimulating agents.

A. Anemia Due to Chronic Kidney Disease (CKD)
Authorization of 12 weeks may be granted for treatment of anemia due to chronic kidney disease in members with pretreatment hemoglobin < 10 g/dL.

B. Anemia Due to Myelosuppressive Chemotherapy
Authorization of 12 weeks may be granted for treatment of anemia due to myelosuppressive chemotherapy in members with nonmyeloid malignancy and pretreatment hemoglobin < 10 g/dL.

C. Anemia in Myelodysplastic Syndrome (MDS)
Authorization of 12 weeks may be granted for treatment of anemia in myelodysplastic syndrome in members with pretreatment hemoglobin < 10 g/dL whose pretreatment serum erythropoietin (EPO) level < 500 mU/mL.

D. Reduction of Allogeneic Red Blood Cell Transfusion in Patients Undergoing Elective, Noncardiac, Nonvascular Surgery
Authorization of 30 days may be granted for reduction of allogenic red blood cell transfusion in members scheduled to have an elective, noncardiac, nonvascular surgery with pretreatment hemoglobin ≤ 13 g/dL.

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

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

G. Anemia Due to Zidovudine in HIV-infected Patients
Authorization of 12 weeks may be granted for treatment of anemia due to zidovudine in HIV-infected members currently receiving zidovudine with pretreatment hemoglobin < 10 g/dL whose pretreatment serum EPO level is < 500 mU/mL.

I. Anemia in Members Whose Religious Beliefs Forbid Blood Transfusions
Authorization of 12 weeks may be granted for treatment of anemia in members whose religious beliefs forbid blood transfusions with pretreatment hemoglobin < 10 g/dL.

J. Anemia in Primary Myelofibrosis (MF), Post-polycythemia Vera MF, or Post-Essential Thrombocythemia MF
Authorization of 12 weeks may be granted for treatment of anemia in primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis in members who meet ALL of the following criteria:
1. Pretreatment hemoglobin < 10 g/dL
2. Pretreatment serum EPO level < 500 mU/mL

K. Anemia Due to Cancer
Authorization of 12 weeks may be granted for treatment of anemia due to cancer in members who have cancer and are undergoing palliative treatment.

III. CONTINUATION OF THERAPY

Note: Requirements regarding current hemoglobin level exclude values due to a recent transfusion. All members must be assessed for iron deficiency anemia and have adequate iron stores (defined as a serum transferrin saturation [TSAT] level greater than or equal to 20% within the prior 3 months) or are receiving iron therapy before continuation of treatment with Epogen/Procrit/Retacrit. Members may not use Epogen/Procrit/Retacrit concomitantly with other erythropoiesis stimulating agents.

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 $\geq$ 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 continued treatment of anemia due to chronic kidney disease in members with current hemoglobin < 12 g/dL.

B. Anemia Due to Myelosuppressive Chemotherapy
Authorization of 12 weeks may be granted for the continued treatment of anemia due to myelosuppressive chemotherapy in members with nonmyeloid malignancy and current hemoglobin < 12 g/dL.

C. Anemia in Myelodysplastic Syndrome (MDS)
Authorization of 12 weeks may be granted for continued treatment of anemia in myelodysplastic syndrome in members with current hemoglobin is < 12 g/dL

D. Anemia in Rheumatoid Arthritis (RA)
Authorization of 12 weeks may be granted for continued treatment of anemia in rheumatoid arthritis with current hemoglobin < 12 g/dL.

E. Anemia Due to Hepatitis C Treatment
Authorization of 12 weeks may be granted for continued treatment of anemia due to Hepatitis C treatment in members who meet 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.

F. Anemia Due to Zidovudine in HIV-infected Patients
Authorization of 12 weeks may be granted for continued treatment of anemia due to zidovudine in HIV-infected members receiving zidovudine with current hemoglobin < 12 g/dL.

G. Anemia in Members Whose Religious Beliefs Forbid Blood Transfusions
Authorization of 12 weeks may be granted for continued treatment of anemia in members whose religious beliefs forbid blood transfusions with current hemoglobin < 12 g/dL.

H. Anemia in Primary Myelofibrosis (MF), Post-polycythemia Vera MF, or Post-Essential Thrombocythemia MF
Authorization of 12 weeks may be granted for continued treatment of anemia in primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis with current hemoglobin < 12 g/dL.

I. Anemia Due to Cancer

Authorization of 12 weeks may be granted for continued treatment of anemia due to cancer in members who have cancer and are undergoing palliative treatment.

IV. REFERENCES

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