Reference number(s)
2110-A

JURISDICTION SPECIFIC MEDICARE PART B

Epogen-Procrit-Retacrit (epoetin alfa)

POLICY

I. COVERED USES

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

A. Anemia in patients with chronic kidney disease
B. Anemia due to myelosuppressive chemotherapy
C. Anemia associated with myelodysplastic syndrome (including chronic myelomonocytic leukemia (CMML))
D. Anemia due to zidovudine in HIV-infected patients
E. Reduction in the need for allogeneic red blood cell transfusions
F. Anemia due to the management of hepatitis C
G. Anemia associated with rheumatoid arthritis

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. DOCUMENTATION

The following documentation must be available, upon request, for all submissions:
A. Support for the medical rationale for treatment including most recent blood pressure, including evidence that elevated pressures are being adequately controlled, weight in kilograms, date and results of hematocrit and hemoglobin levels prior to the initiation of erythropoiesis stimulating agent therapy and assessment that rules out other causative factors of anemia
B. Most recent hematocrit and hemoglobin reading
C. Documentation that hemoglobin and hematocrit levels are documented at the frequencies outlined for each indication and that doses are being titrated or withheld/re-initiated according to the requirements of federal regulations
D. Dose of epoetin alfa and route of administration
E. For anemia due to myelodysplastic syndrome only- a bone marrow biopsy or aspiration report confirming the diagnosis

III. EXCEPTIONS

The following exceptions applies to all requests:
A. The member must not have uncontrolled hypertension.
B. The member must not have a known hypersensitivity to mammalian cell-derived products or to albumin.

C. Prior to initiating therapy, all other causes of anemia have been managed or ruled out.
D. The member's iron status must be monitored before and during treatment.

IV. CRITERIA FOR APPROVAL

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

A. Anemia in chronic kidney disease

1. Authorization of 16 weeks may be granted for the treatment of anemia in members with chronic kidney disease who are not receiving erythropoiesis stimulating agents (ESA) when all of the following criteria are met:
   i. The member is not receiving dialysis.
   ii. The member's iron stores have been assessed and the transferrin saturation is greater than or equal to 20 percent and the members ferritin level are 100 ng/mL or greater.
   iii. The member's starting dose does not exceed 100 units per kilogram three times weekly.
   iv. The member will have hemoglobin levels assessed at least weekly until stable then monthly.
   v. The pre-treatment hemoglobin level is less than 10 g/dL.
2. Authorization of 12 months may be granted for the continuation of therapy for anemia in members with chronic kidney disease who are receiving ESA therapy when all of the following criteria are met:
   i. The member is not receiving dialysis.
   ii. The member's iron stores have been assessed and the transferrin saturation is greater than or equal to 20 percent and the member's ferritin level are 100 ng/mL or greater.
   iii. The member's hemoglobin has responded to therapy by increasing 1 g/dL after 12 weeks of therapy.
   iv. The dose will be reduced or interrupted if the hemoglobin exceeds 12 g/dL.

B. Anemia due to myelosuppressive chemotherapy

1. Authorization of 16 weeks may be granted for the treatment of anemia due to myelosuppressive chemotherapy in members who are not receiving erythropoiesis stimulating agents (ESA) when all of the following criteria are met:
   i. The member is receiving myelosuppressive chemotherapy for the treatment of cancer
   ii. The member's anemia is not due to any of the following issues: folate deficiency, B-12 deficiency, iron deficiency, hemolysis, bleeding, or bone marrow fibrosis.
   iii. The member is not being treated for acute or chronic myelogenous leukemia (AML, CML) or erythroid cancers.
   iv. The member is not being treated for anemia of cancer that is not related to cancer treatment.
   v. The member is not being treated with radiotherapy only.
   vi. The member is not using this prophylactically to prevent chemotherapy-induced anemia.
   vii. The member is not using this prophylactically to reduce tumor hypoxia.
   viii. The member does not have anemia due to erythropoietin-type antibodies.
   ix. The member does not have the anticipated outcome of cure.
   x. The member has either a hematocrit of 30% or less or a hematocrit of greater than 30% with a hemoglobin of less than 10 g/dL.
   xi. The starting dose does not exceed 150 units per kilogram three times a week or 40,000 units once weekly.
   xii. Therapy will be discontinued after 8 weeks if the hemoglobin has not responded by at least an increase of 1 g/dL.

2. Authorization of 12 months may be granted for the continuation of therapy for anemia due to myelosuppressive chemotherapy in members who are receiving ESA therapy when all of the following criteria are met:
   i. The member has responded to treatment by increases in hemoglobin levels of at least 1 g/dL over baseline or increases in hematocrit levels of greater than 3% over baseline.
   ii. The duration of therapy must not extend beyond 8 weeks after the final dose of chemotherapy.

C. Anemia associated with myelodysplastic syndrome (including chronic myelomonocytic leukemia (CMML))

Authorization of 12 months may be granted for the treatment of anemia associated with myelodysplastic syndrome, including chronic myelomonocytic leukemia.

D. Anemia due to zidovudine in HIV-infected members

1. Authorization of 12 months may be granted for treatment of anemia due to zidovudine in HIV-infected members who are not receiving erythropoiesis stimulating agents (ESA) when all of the following criteria are met:
   i. The member is currently receiving zidovudine.
   ii. The member has a pretreatment serum erythropoietin level of less than or equal to 500 mU per mL.
   iii. The initial dose does not exceed 100 units per kilogram three times per week.
2. Authorization of 12 months may be granted for continuation of therapy for anemia due to zidovudine in HIV-infected members who are receiving ESA therapy when all of the following criteria are met:
   i. The member is currently receiving zidovudine.
   ii. The member has a pretreatment serum erythropoietin level of less than or equal to 500 mU per mL.
   iii. The dose does not exceed 300 units/kg three times a week.
   iv. The member's hemoglobin is less than 12 g/dL OR the members hemoglobin is 12 g/dL or greater and therapy will be held or reduced until the hemoglobin falls below 11 g/dL.

E. Reduce the need for allogenic red blood cell transfusion

Authorization of 4 weeks may be granted to reduce the need for allogenic red blood cell transfusion when all of the following criteria are met:

1. The member is not undergoing cardiac or vascular surgery.
2. The member will not donate autologous blood in advance for a scheduled surgery.
3. The member's hemoglobin is greater than 10 g/dL but less than 13 g/dL.
4. The member must be prescribed one of the following dosing regimens: 300 units per kilogram per day for 15 days total: administered daily for 10 days before surgery, on the day of surgery, and for 4 days after surgery OR 600 Units per kilogram administered 21, 14, and 7 days before surgery and on the day of surgery.

F. Anemia due to the management of hepatitis C

Authorization of 16 weeks may be granted for treatment of anemia due to the management of hepatitis C when the member is currently receiving treatment for hepatitis C with the combination of ribavirin and interferon alfa or ribavirin and peginterferon alfa.

G. Anemia associated rheumatoid arthritis

Authorization of 12 months may be granted for treatment of anemia associated with rheumatoid arthritis when the member has been diagnosed with rheumatoid arthritis using the American College of Rheumatology criteria.

V. REFERENCES

1. Erythropoiesis Stimulating Agents LCD (L36276) Version R11. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed September 10, 2021.
2. Billing and Coding: Erythropoiesis Stimulating Agents (A57628) Version 3. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed September 10, 2021.
3. National Coverage Determination (NCD) for Erythropoiesis Stimulating Agents (ESAs) in Cancer and Related Neoplastic Conditions (110.21). https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=322&ncdver=1&DocID=110.21&bc=gAAAABAAAAAAAA%3d%3d&. Accessed September 10, 2021.

