

Jurisdiction Specific Medicare Part B Epogen-Procrit-Retacrit-Aranesp

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Epogen	epoetin alfa
Procrit	epoetin alfa
Retacrit	epoetin alfa-epbx
Aranesp	darbepoetin alfa

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.

- Anemia in patients with end stage renal disease (ESRD) on dialysis
- Anemia in patients with chronic kidney disease (CKD) not on dialysis
- Anemia associated with cancer and related neoplastic conditions
- Anemia related to therapy with zidovudine (AZT)
- Anemia associated with chemotherapeutic medications
- Anemia due to myelodysplastic syndrome (MDS)
- Anemia of chronic disease
- Prophylactic pre-operative use for reduction of allogenic blood transfusions prior to elective hip and knee replacement surgery
- Prophylactic pre-operative use for reduction of allogenic blood transfusions prior to elective noncardiac or nonvascular surgery
- Anemia due to myelofibrosis

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4844-A

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

Exclusions

Coverage will not be provided for members with any of the following exclusions:

- Any anemia in cancer or cancer treatment patients due to folate deficiency, B-12 deficiency, iron deficiency, hemolysis, bleeding, or bone marrow fibrosis.
- The anemia associated with the treatment of acute and chronic myelogenous leukemias (CML, AML), or erythroid cancers.
- The anemia of cancer not related to cancer treatment.
- Any anemia associated only with radiotherapy.
- Prophylactic use to prevent chemotherapy-induced anemia.
- Prophylactic use to reduce tumor hypoxia.
- Patients with erythropoietin-type resistance due to neutralizing antibodies.
- Anemia due to cancer treatment if patients have uncontrolled hypertension.
- ESA use to replace red blood cell (RBC) transfusion in members who need immediate urgent correction of anemia.

Coverage Criteria

Anemia in end stage renal disease (ESRD)

Authorization of 12 weeks may be granted for the treatment of anemia in members with ESRD who are on dialysis when the pretreatment hemoglobin level is less than 10 g/dL (or hematocrit is less than 30%).

Anemia in chronic kidney disease (CKD)

Authorization of 12 weeks may be granted for the treatment of anemia in members with CKD who are not on dialysis when the pretreatment hemoglobin level is less than 10 g/dL (or hematocrit is less than 30%) and the member meets one of the following criteria:

- Serum creatinine is greater than or equal to 3 mg/dL.
- Creatinine clearance is less than 60 mL/min.
- Glomerular filtration rate (GFR) is less than 60 mL/min/1.73m².

Anemia associated with cancer and related neoplastic conditions

Authorization of 8 weeks may be granted for the treatment of anemia in members with cancer and related neoplastic conditions when the member's pretreatment hemoglobin level is less than 10 g/dL (or hematocrit is less than 30%) and when all of the following criteria are met:

- The starting dose will not exceed 150 units/kg three times weekly for epoetin and 2.25 mcg/kg once weekly for Aranesp.
- The provider will follow the following for maintenance of therapy:
 - For members whose hemoglobin level remains below 10 g/dL (or hematocrit is less than 30%) four weeks after initiation of therapy and the rise in hemoglobin is greater than or equal to 1 g/dL (or hematocrit rise of greater than or equal to 3%), the maintenance dose of ESA therapy is the starting dose.
 - For members whose hemoglobin rises less than 1 g/dL (hematocrit rise less than 3%) compared to pretreatment baseline over 4 weeks of treatment and whose hemoglobin level remains less than 10 g/dL after the 4 weeks of treatment (or the hematocrit is less than 30%), the recommended FDA label starting dose may be increased once by 25%.
 - The provider will not continue the requested drug if there is a rapid rise in hemoglobin greater than 1 g/dL (hematocrit greater than 3%) over 2 weeks of treatment unless the hemoglobin remains below or subsequently falls to less than 10 g/dL (or the hematocrit is less than 30%). Continuation and reinstatement of therapy must include a dose reduction of 25% from the previously administered dose.
- ESA treatment duration for each course of chemotherapy includes the 8 weeks following the final dose of myelosuppressive chemotherapy in a chemotherapy regimen.

Authorization of 12 months may be granted for the continuation of therapy for the treatment of anemia in members with cancer and related neoplastic conditions when both of the following criteria are met:

- The member has responded to treatment by increases in hemoglobin levels of at least 1 g/dL (or hematocrit levels greater than 3%) over baseline.
- ESA treatment duration for each course of chemotherapy includes the 8 weeks following the final dose of myelosuppressive chemotherapy in a chemotherapy regimen.

Anemia related to therapy with zidovudine (AZT)

Authorization of 12 months may be granted for the treatment of anemia in members with acquired immunodeficiency syndrome (AIDS) or AIDS related complex (ARC) who are taking zidovudine (AZT) and/or other nucleoside reverse transcriptase inhibitors (NRTI) when the member's pretreatment hemoglobin level is less than 10 g/dL (or hematocrit is less than 30%).

Anemia associated with chemotherapeutic medications

Authorization of 12 weeks may be granted for the treatment of anemia associated with chemotherapeutic medications for a non-cancer diagnosis or following stem cell transplantation and associated

immunosuppression when the member's pretreatment hemoglobin level is less than 10 g/dL (or hematocrit is less than 30%).

Anemia due to myelodysplastic syndrome (including myelofibrosis)

Authorization of 12 weeks may be granted for treatment of anemia due to myelodysplastic syndrome (including myelofibrosis) when the member meets all of the following criteria:

- The member's diagnosis was confirmed with a bone marrow biopsy.
- The member has anemia that is symptomatic.
- The member has a reasonable expectancy of longer survival.
- The member will have a reduced need or no need for transfusions.
- The member has a hemoglobin level is less than or equal to 10 g/dL (or hematocrit is less than 30%) one week before the initial injection.
- The member's pretreatment erythropoietin (EPO) level is less than or equal to 500 mU/mL.

Anemia of chronic disease

Authorization of 12 weeks may be granted for the treatment of anemia of chronic disease for members with rheumatoid arthritis, systemic lupus erythematosus, chronic hepatitis C, Crohn's disease or ulcerative colitis when the member meets all of the following criteria:

- The member has a pretreatment hematocrit less than or equal to 30% and/or has been transfusion dependent.
- The member has a pretreatment EPO level of 100 mU/mL or less.
- The member meets one of the following conditions:
 - Low or normal serum iron.
 - Low or normal iron binding capacity.
 - Normal or elevated serum ferritin.
 - Adequate iron stores in bone marrow.

Prophylactic pre-operative use for reduction of allogenic blood transfusions prior to elective hip and knee replacement surgery

Authorization of 8 weeks may be granted to reduce the risk of transfusion in members prior to surgery when the member meets all of the following criteria:

- The member is undergoing hip or knee surgery.
- The member has anemia with a hemoglobin between 10 g/dL and 13 g/dL three weeks before surgery.
- The member is not a candidate for autologous blood transfusions.
- The member is expected to lose more than 2 units of blood.
- The member has chronic anemia.

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Prophylactic pre-operative use for reduction of allogenic blood transfusions prior to elective noncardiac or nonvascular surgery

Authorization of 8 weeks may be granted to reduce the risk of transfusion in members prior to surgery when the member meets all of the following criteria:

- The member is undergoing elective noncardiac or nonvascular surgery.
- The member has anemia with a hemoglobin greater than 10 g/dL to less than 13 g/dL.
- The member is not a candidate for autologous blood transfusions.

References

1. Erythropoiesis Stimulating Agents LCD (L34633) Version R24. Available at: <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx>. Accessed September 9, 2024.
2. Billing and Coding: Erythropoiesis Stimulating Agents (A56795) Version R12. Available at: <https://www.cms.gov/medicare-coverage-database/details/article-details.aspx>. Accessed September 9, 2024.
3. National Coverage Determination (NCD) for Erythropoiesis Stimulating Agents (ESAs) in Cancer and Related Neoplastic Conditions (110.21). Version 1. <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx>. Accessed September 9, 2024.
4. Epogen [package insert]. Thousand Oaks, CA: Amgen Inc.; April 2024.
5. Procrit [package insert]. Horsham, PA: Janssen Products.; July 2018.
6. Retacrit [package insert]. Lake Forest, IL: Hospira Inc.; June 2024.
7. Aranesp [package insert]. Thousand Oaks, CA: Amgen Inc.; April 2024.