



EXPRESS SCRIPTS®

PRIOR AUTHORIZATION POLICY

POLICY: Erythroid Stimulating Agents – Epoetin Alfa Products

- Epogen® (epoetin alfa injection for intravenous or subcutaneous use – Amgen)
- Procrit® (epoetin alfa injection for intravenous or subcutaneous use – Janssen)
- Retacrit™ (epoetin alfa-epbx injection for intravenous and subcutaneous use – Pfizer/Hospira)

TAC APPROVAL DATE: 07/24/2019

OVERVIEW

Epoetin alfa products are erythropoiesis-stimulating proteins manufactured by recombinant DNA technology that are administered by intravenous (IV) injection or subcutaneous (SC) injection.¹⁻³ The agents are also known as erythropoiesis-stimulating agents (ESAs). Retacrit is the first biosimilar epoetin alfa product. Epoetin alfa has indications for: 1) 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) transfusions; 2) the treatment of anemia due to zidovudine in human immunodeficiency virus (HIV)-infected patients; 3) the treatment of anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitant myelosuppressive chemotherapy; and 4) the reduction of allogeneic RBC transfusions in patients with perioperative hemoglobin (Hb) > 10.0 to ≤ 13.0 g/dL who at high risk for perioperative blood loss from elective, noncardiac, nonvascular surgery. Epoetin alfa has not been shown to improve quality of life, fatigue, or patient well-being. The prescribing information notes that it is not indicated for use in: 1) patients with cancer receiving hormonal agents, biologic products, or radiotherapy, unless they are also receiving concomitant myelosuppressive chemotherapy; 2) in those with cancer given myelosuppressive chemotherapy when the anticipated outcome is cure; 3) in patients with cancer receiving myelosuppressive chemotherapy in whom the anemia can be managed by transfusion; 4) in those scheduled for surgery who are willing to donate autologous blood; 5) in those undergoing cardiac or vascular surgery; and 6) as a substitute for RBC transfusions in patients who require immediate correction of anemia.

The prescribing information for epoetin alfa recommends that therapy should be initiated for patients with CKD on dialysis when the Hb level is < 10.0 g/dL and if the Hb level approaches or exceeds 11.0 g/dL, reduce or interrupt the dose of epoetin alfa. For adults with CKD who are not on dialysis, epoetin alfa should be initiated when the Hb is < 10.0 g/dL and other considerations apply (e.g., patient is likely to need transfusions). If the Hb exceeds 10.0 g/dL, reduce or interrupt the epoetin alfa dose and use the lowest dose sufficient to reduce the need for RBC transfusions. Epoetin alfa is indicated for the treatment of anemia due to zidovudine given at ≤ 4,200 mg per week in HIV-infected patients with endogenous serum erythropoietin levels of ≤ 500 mUnits/mL. It is recommended to withhold epoetin alfa if Hb exceeds 12.0 g/dL. Data show that epoetin alfa elevated or maintained Hb and/or hematocrit and decreased transfusions in anemic patients (Hb < 10.0 g/dL) who were receiving zidovudine. Patients with baseline endogenous serum erythropoietin levels ≤ 500 mUnits/mL derived greater benefit with epoetin alfa (e.g., achievement of higher hematocrit, reduction in transfusion requirements) compared with those having levels greater than this threshold. A published randomized, multicenter, double-blind, placebo-controlled, 3-month clinical trial involving 63 patients with HIV receiving zidovudine also found similar results.⁴ Initiate epoetin alfa for patients on cancer chemotherapy only if the Hb is < 10.0 g/dL. Use the lowest dose of epoetin alfa necessary to avoid RBC transfusions. Hb can be increased to (or near) a concentration of 12.0 g/dL at which time the dose of epoetin alfa should be titrated to maintain that level.

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Guidelines

The Kidney Disease Improving Global Outcomes (KDIGO) clinical practice guidelines for anemia in CKD (2012) state that for adults with CKD on dialysis ESA therapy should be used to avoid having the Hb concentration fall below 9.0 g/dL by initiating ESA therapy when the Hb is between 9.0 and 10.0 g/dL.⁵ The guidelines recommend against ESA therapy for adult patients with CKD who are not on dialysis when Hb levels are ≥ 10.0 g/dL. For adults with CKD who are not on dialysis with Hb levels < 10.0 g/dL, the decision whether to initiate ESA therapy should be individualized based on many factors (e.g., prior response to iron therapy, the risk of needing a transfusion, presence of symptoms). In general, ESAs should not be used to maintain Hb concentrations above 11.5 g/dL in adult patients with CKD. For pediatric patients with CKD, the Hb concentration in which ESAs should be initiated in the individual patient should be considered while being aware of the potential benefits and potential harms. In all pediatric patients with CKD receiving ESA therapy the selected Hb concentration should be in the range of 11.0 to 12.0 g/dL. Iron supplementation can improve response to ESA therapy.^{6,7} Baseline and periodic monitoring (e.g., iron, total iron-binding capacity, transferrin saturation, or ferritin levels) and instituting iron replacement when needed may be useful in limiting the need for ESAs, maximizing symptomatic improvement in patients, and determining the reason for failure to adequately respond to ESAs.⁶ Iron deficiency can occur following continued ESA use and, therefore, iron supplementation is required in most patients to maintain an optimal response.

Clinical practice guidelines from the National Comprehensive Cancer Network (NCCN) for myelodysplastic syndrome (MDS) [version 2.2019 – October 18, 2018] list epoetin alfa as having a role in anemic, symptomatic patients with MDS if serum erythropoietin levels are ≤ 500 mU/mL.⁸ Iron stores should be adequate. Due to safety issues, the guidelines suggest that ESAs be used in the management of symptomatic anemia in patients with MDS and to aim for a target Hb ≤ 12 g/dL. Data suggest epoetin alfa may provide some benefits in MDS.⁹⁻¹⁴ The NCCN guidelines for myeloproliferative disorders (version 2.2019 – October 29, 2018) address epoetin alfa products as options for treatment with of patients with anemia related to myelofibrosis having a serum erythropoietin level ≤ 500 mU/mL.¹⁵ Iron stores should be adequate. The guidelines also advise that ESAs are not effective for the management of transfusion-dependent anemia.

Safety

Epoetin alfa has a Boxed Warning that ESAs increase the risk of death, myocardial infarction (MI), stroke, venous thromboembolism, thrombosis of vascular access and tumor progression or recurrence.¹⁻³ For patients with CKD, controlled trials have demonstrated that patients experienced greater risks for death, serious adverse cardiovascular (CV) reactions, and stroke when given ESAs to target a Hb level > 11.0 g/dL. No trial has identified a Hb target level, ESA dose, or dosing strategy that negates such risks. Use the lowest epoetin alfa dose necessary to reduce the need for RBC transfusions. For use in cancer, ESAs shorten overall survival and/or increase the risk of tumor progression or recurrence in clinical studies involving patients with breast, non-small cell lung, head and neck, lymphoid, and cervical cancers. Use the lowest dose needed to avoid RBC transfusions. Use ESAs only for anemia due to myelosuppressive chemotherapy. ESAs are not indicated for patients receiving myelosuppressive chemotherapy when the anticipated outcome is cure. Discontinue ESAs after the completion of a chemotherapy course. In surgery patients, deep vein thrombosis (DVT) prophylaxis is recommended due to the increased risk of DVT.¹⁻³

POLICY STATEMENT

Prior authorization is recommended for prescription benefit coverage of epoetin alfa. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is

equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with epoetin alfa as well as the monitoring required for adverse events and long-term efficacy, approval requires epoetin alfa to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of epoetin alfa is recommended in those who meet the following criteria:

FDA-Approved Indications

- 1. Anemia in Patients with Chronic Kidney Disease (CKD) who are on Dialysis.** Approve for 1 year if the patient meets the following criteria (A or B):
 - A) Initial Therapy.** Approve if the patient meets the following criteria (i and ii):
 - i.** The patient meets one of the following (a or b):
 - a)** The patient is ≥ 18 years of age with a hemoglobin < 10.0 g/dL; OR
 - b)** The patient is < 18 years of age with a hemoglobin ≤ 11.0 g/dL; AND
 - ii.** The patient meets one of the following (a or b):
 - a)** The patient is currently receiving iron therapy; OR
 - b)** The patient has adequate iron stores according to the prescriber; OR
 - B) Patient is currently receiving an erythropoiesis-stimulating agent (ESA).** Note: Examples of erythropoiesis-stimulating agents include an epoetin alfa product (e.g., Epogen, Procrit, or Retacrit), a darbepoetin alfa product (e.g., Aranesp), or a methoxy polyethylene glycol-epoetin beta product (e.g., Mircera). Approve if the patient meets the following criteria (i and ii):
 - i.** The patient meets one of the following (a or b):
 - a)** The patient is ≥ 18 years of age with a hemoglobin < 11.5 g/dL; OR
 - b)** The patient is < 18 years of age with a hemoglobin ≤ 12.0 g/dL; AND
 - ii.** The patient meets one of the following (a or b):
 - a)** The patient is currently receiving iron therapy; OR
 - b)** The patient has adequate iron stores according to the prescriber.

- 2. Anemia in Patients with Chronic Kidney Disease (CKD) who are not on Dialysis.** Approve for 1 year if the patient meets the following criteria (A or B):
 - A) Initial Therapy.** Approve if the patient meets the following criteria (i and ii):
 - i.** The patient meets one of the following (a or b):
 - a)** The patient is ≥ 18 years of age with a hemoglobin < 10.0 g/dL; OR
 - b)** The patient is < 18 years of age with a hemoglobin ≤ 11.0 g/dL; AND
 - ii.** The patient meets one of the following (a or b):
 - a)** The patient is currently receiving iron therapy; OR
 - b)** The patient has adequate iron stores according to the prescriber; OR
 - B) Patient is currently receiving an erythropoiesis-stimulating agent (ESA).** Note: Examples of erythropoiesis-stimulating agents include an epoetin alfa product (e.g., Epogen, Procrit, or Retacrit), a darbepoetin alfa product (e.g., Aranesp), or a methoxy polyethylene glycol-epoetin beta product (e.g., Mircera). Approve if the patient meets the following criteria (i and ii):
 - i.** The patient meets one of the following (a or b):

- a) The patient is ≥ 18 years of age with a hemoglobin < 11.5 g/dL; OR
 - b) The patient is < 18 years of age with a hemoglobin ≤ 12.0 g/dL; AND
 - ii. The patient meets one of the following (a or b):
 - a) The patient is currently receiving iron therapy; OR
 - b) The patient has adequate iron stores according to the prescriber.
- 3. **Anemia in Patients with Cancer due to Cancer Chemotherapy.** Approve for 6 months if the patient meets the following criteria (A or B):
 - A) Initial Therapy. Approve if the patient meets the following criteria (i, ii, and iii):
 - i. The patient has a hemoglobin < 10.0 g/dL; AND
 - ii. The patient is currently receiving myelosuppressive chemotherapy; AND
 - iii. The patient meets one of the following (a or b):
 - a) The patient is currently receiving iron therapy; OR
 - b) The patient has adequate iron stores according to the prescriber.
 - B) Patient is currently receiving an erythropoiesis-stimulating agent (ESA). Note: Examples of erythropoiesis-stimulating agents include an epoetin alfa product (e.g., Epogen, Procrit, or Retacrit), or a darbepoetin alfa product (e.g., Aranesp). Approve if the patient meets the following criteria (i, ii, and iii):
 - i. The patient has a hemoglobin ≤ 12.0 g/dL; AND
 - ii. The patient is currently receiving myelosuppressive chemotherapy; AND
 - iii. The patient meets one of the following (a or b):
 - a) The patient is currently receiving iron therapy; OR
 - b) The patient has adequate iron stores according to the prescriber.
- 4. **Patients with Anemia and Human Immunodeficiency Virus (HIV) who are Receiving Zidovudine.** Approve for 1 year if the patient meets the following criteria (A or B):
 - A) Initial Therapy. Approve if the patient meets the following criteria (i, ii, and iii):
 - i. The patient meets one of the following (a or b):
 - a) The patient has a hemoglobin < 10.0 g/dL; OR
 - b) The patient has a serum erythropoietin level is ≤ 500 mU/mL; AND
 - ii. The patient is currently receiving zidovudine therapy; AND
 - iii. The patient meets one of the following (a or b):
 - a) The patient is currently receiving iron therapy; OR
 - b) The patient has adequate iron stores according to the prescriber; OR
 - B) Patient is currently receiving an erythropoiesis-stimulating agent (ESA). Note: Examples of erythropoiesis-stimulating agents include an epoetin alfa product (e.g., Epogen, Procrit, or Retacrit), or darbepoetin alfa product (e.g., Aranesp). Approve if the patient meets the following criteria (i, ii, and iii):
 - i. The patient has a hemoglobin ≤ 12.0 g/dL; AND
 - ii. The patient is currently receiving zidovudine therapy; AND
 - iii. The patient meets one of the following (a or b):
 - a) The patient is currently receiving iron therapy; OR
 - b) The patient has adequate iron stores according to the prescriber.
- 5. **Reduction of Allogeneic Red Blood Cell (RBC) Transfusions in Patients Undergoing Surgery.** Approve for 1 month if the patient meets the following criteria (A, B, C and D):
 - A) Hemoglobin is ≤ 13.0 g/dL; AND

- B) The surgery is elective, nonvascular and noncardiac; AND
- C) The patient is not willing or able to donate autologous blood prior to surgery; AND
- D) The patient meets one of the following (i or ii):
 - i. The patient is currently receiving iron therapy; OR
 - ii. The patient has adequate iron stores according to the prescriber.

Other Uses with Supportive Evidence

6. **Anemia Associated with Myelodysplastic Syndrome (MDS).** Approve for 1 year if the patient meets the following criteria (A or B):

- A) **Initial Therapy.** Approve if the patient meets the following criteria (i, ii, iii, and iv):
 - i. The patient meets one of the following (a or b):
 - a) The patient has a hemoglobin < 10.0 g/dL; OR
 - b) The patient has a serum erythropoietin level is \leq 500 mU/mL; AND
 - ii. Patient is \geq 18 years of age; AND
 - iii. Aranesp is prescribed by, or in consultation with, a hematologist or oncologist; AND
 - iv. The patient meets one of the following (a or b):
 - a) The patient is currently receiving iron therapy; OR
 - b) The patient has adequate iron stores according to the prescriber; OR
- B) **Patient is currently receiving an erythropoiesis-stimulating agent (ESA).** Note: Examples of erythropoiesis-stimulating agents include an epoetin alfa product (e.g., Epogen, Procrit, or Retacrit), or a darbepoetin alfa product (e.g., Aranesp). Approve if the patient meets the following criteria (i, ii, iii, and iv):
 - i. The patient has a hemoglobin \leq 12.0 g/dL; AND
 - ii. Patient is \geq 18 years of age; AND
 - iii. Aranesp is prescribed by, or in consultation with, a hematologist or oncologist; AND
 - iv. The patient meets one of the following (a or b):
 - a) The patient is currently receiving iron therapy; OR
 - b) The patient has adequate iron stores according to the prescriber.

7. **Anemia Associated with Myelofibrosis.** Approve for the duration noted below if the patient meets the following criteria (A or B):

- A) **Initial Therapy.** Approve for 3 months if the patient meets the following criteria (i, ii, and iii):
 - i. The patient meets one of the following (a or b):
 - a) The patient has a hemoglobin < 10.0 g/dL; OR
 - b) The patient has a serum erythropoietin level is \leq 500 mU/mL; AND
 - ii. The agent is prescribed by, or in consultation with, a hematologist or oncologist; AND
 - iii. The patient meets one of the following (a or b):
 - a) The patient is currently receiving iron therapy; OR
 - b) The patient has adequate iron stores according to the prescriber; OR
- B) **The patient is currently receiving and erythropoiesis-stimulating agent (ESA) therapy.** Note: Examples of erythropoiesis-stimulating agents include an epoetin alfa product (e.g., Epogen, Procrit, or Retacrit), or a darbepoetin alfa product (e.g., Aranesp); OR Approve for 1 year if the patient meets the following criteria (i, ii, iii, and iv):
 - i. The patient has a hemoglobin \leq 12.0 g/dL; AND
 - ii. The ESA therapy is prescribed by, or in consultation with, a hematologist or oncologist; AND

- iii. The patient meets one of the following (a or b):
 - a) The patient is currently receiving iron therapy; OR
 - b) The patient has adequate iron stores according to the prescriber; AND
- iv. According to the prescriber the patient has had a response defined as Hb \geq 10.0 g/dL or an increase of \geq 2 g/dL.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Epoetin alfa has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

1. **Anemia Associated with Cancer in Patients not Receiving Myelosuppressive Cancer Chemotherapy.** Epoetin alfa is not indicated in patients with cancer who are not receiving cancer chemotherapy.¹⁻³ The American Society of Clinical Oncology/American Society of Hematology guidelines for the use of ESAs in adult patients with cancer recommend against ESA use for treatment of anemia associated with malignancy in those who are not receiving concurrent myelosuppressive chemotherapy.⁶
2. **Anemia Associated with Acute Myeloid Leukemia (AML), Chronic Myelogenous Leukemia (CML) or other Myeloid Cancers.** Epoetin alfa is indicated for use in non-myeloid cancers. AML and CML are examples of myeloid cancers.¹⁻³
3. **Anemia Associated with Radiotherapy in Cancer.** Epoetin alfa is not indicated for use in patients with cancer who are only given radiation therapy.¹⁻³
4. **To Enhance Athletic Performance.** Epoetin alfa is not recommended for approval because this indication is excluded from coverage in a typical pharmacy benefit.
5. **Anemia due to Acute Blood Loss.** Use of epoetin alfa is not appropriate in these types of situations.
6. **Non-Anemic Patients (Hemoglobin [Hb] > 13.0 g/dL) Prior to Surgery.** Although studies have been done that involved non-anemic patients undergoing various surgeries receiving epoetin alfa preoperatively and sometimes postoperatively to prevent transfusions or subsequent anemia, the overall benefit of this therapy in those with relatively normal preoperative Hb level is questionable.
7. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

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HISTORY

Type of Revision	Summary of Changes*	TAC Approval Date
Annual revision	No criteria changes.	06/14/2017
Annual revision	Added Retacrit to the policies with the same approval criteria to that of Epogen and Procrit. The name of the policy was changed from Epogen/Procrit to Epoetin Alfa Products. Criteria that previously stated Epogen/Procrit were changed to state epoetin alfa. Criteria were revised to reflect FDA-approval of Mircera for use in the treatment of anemia associated with chronic kidney disease in pediatric patients who are on hemodialysis. For patients requesting to use epoetin alfa who are currently receiving Mircera, the target Hb of ≤ 12.0 g/dL was added for children, similar to the other ESAs. Previous, the criteria only addressed the hemoglobin threshold in adults (≤ 11.5 g/dL) who were receiving Mircera and requesting to transition to epoetin alfa.	06/20/2018

HISTORY (CONTINUED)

Type of Revision	Summary of Changes*	TAC Approval Date
Annual revision	<p>The following changes were made:</p> <ol style="list-style-type: none"> 1. Anemia in CKD for Patients Who are on Dialysis: The approval duration was changed from 6 months to 1 year. For the criteria that requires the patient have a specified Hb value, changed the wording of “adults” to “patients ≥ 18 years of age”. For the criteria that requires children to have a specified Hb value, changed the wording of “children” to “patients < 18 years of age”. For the criteria that addresses patients who are currently receiving an ESA, changed from citing examples of the ESA products in criteria to providing a list of ESAs in a note. The example cited that the “Epoetin alfa prescribing information recommends supplemental iron therapy when serum ferritin is < 100 mcg/L or when serum transferrin saturation is < 20%” was deleted. 2. Anemia in CKD for Patients Who are Not on Dialysis: The approval duration was changed from 6 months to 1 year. For the criteria that requires the patient have a specified Hb value, changed the wording of “adults” to “patients ≥ 18 years of age”. For the criteria that requires children to have a specified Hb value, changed the wording of “children” to “patients < 18 years of age”. For the criteria that addresses patients who are currently receiving an ESA, changed from citing examples of the ESA products in criteria to providing a list of ESAs in a note. The example cited that the “Epoetin alfa prescribing information recommends supplemental iron therapy when serum ferritin is < 100 mcg/L or when serum transferrin saturation is < 20%” was deleted. 3. Patients with Anemia and HIV who are Receiving Zidovudine: The duration of therapy was changed from 4 months to 1 year. For the criteria that addresses patients who are currently receiving an ESA, changed from citing examples of the ESA products in criteria to providing a list of ESAs in a note. The example cited that the “Epoetin alfa prescribing information recommends supplemental iron therapy when serum ferritin is < 100 mcg/L or when serum transferrin saturation is < 20%” was deleted. 4. Anemia in Patients with Cancer Due to Cancer Chemotherapy: The approval duration was changed from 4 months to 6 months. For the criteria that addresses patients who are currently receiving an ESA, changed from citing examples of the ESA products in criteria to providing a list of ESAs in a note. The example cited that the “Epoetin alfa prescribing information recommends supplemental iron therapy when serum ferritin is < 100 mcg/L or when serum transferrin saturation is < 20%” was deleted. 5. Reduction of Allogeneic Red Blood Cell Transfusions in Patients Undergoing Surgery: The example cited that the “Epoetin alfa prescribing information recommends supplemental iron therapy when serum ferritin is < 100 mcg/L or when serum transferrin saturation is < 20%” was deleted. 6. Anemia Associated with MDS: The approval duration was changed from 6 months to 1 year. For the criteria that addresses patients who are currently receiving an ESA, changed from citing examples of the ESA products in criteria to providing a list of ESAs in a note. 7. Anemia Associated with Myelofibrosis: New criteria were approved. See policy. 	07/24/2019

* For a further summary of criteria changes, refer to respective TAC minutes available at: <http://esidepartments/sites/Dep043/Committees/TAC/Forms/AllItems.aspx>; TAC – Therapeutic Assessment Committee; Hb – Hemoglobin; ESA(s) – Erythroid stimulating agent(s); CKD – Chronic kidney disease; Hb – Hemoglobin; HIV – Human immunodeficiency virus; MDS – Myelodysplastic syndrome.