POLICY Document for EPOGEN (epoetin alfa)

The overall objective of this policy is to support the appropriate and cost-effective use of the medication, specific to use of preferred medication options, and overall, clinically appropriate use. This document provides specific information to both sections of the overall policy.

Section 1: Preferred Product
- Policy information specific to preferred medications

Section 2: Clinical Criteria
- Policy information specific to the clinical appropriateness for the medication

Section 1: Preferred Product

CAREFIRST: EXCEPTIONS CRITERIA
ERYTHROPOIESIS STIMULATING AGENTS
PREFERRED PRODUCTS: ARANESP, RETACRIT, PROCRIT

POLICY
This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY

This program applies to the erythropoiesis stimulating agents specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred products and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to all members who are requesting treatment with the targeted products.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Erythropoiesis stimulating agents

	Product(s)
Preferred*	• **Aranesp** (darbepoetin alfa) • **Procrit** (epoetin alfa) • **Retacrit** (epoetin alfa-epbx)
Targeted	• **Epogen** (epoetin alfa) • **Mircera** (methoxy polyethylene glycol-epoetin beta)

*: Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

II. EXCEPTION CRITERIA

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred products.

A. Mircera

1. The request is for anemia due to chronic kidney disease

2. Coverage for the targeted product is provided when the member has a documented inadequate response or intolerable adverse event with all of the preferred products.

B. Epogen

Coverage for the targeted products are provided when both of the following criteria are met:

1. Member has had a documented intolerable adverse event with the preferred product, Retacrit and Procrit, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.
2. Member has experienced a documented inadequate response or intolerable adverse event with the preferred product, Aranesp, when prescribed for the treatment of anemia due to chronic kidney disease or the treatment of anemia due to myelosuppressive chemotherapy in cancer.

Section 2: Clinical Criteria

Specialty Guideline Management Epogen-Procrit-Retacrit

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

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.

FDA-approved Indications[1-3]

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.

Treatment of anemia due to zidovudine administered at less than or equal to 4200 milligrams (mg) per week in patients with human immunodeficiency virus (HIV)-infection with endogenous serum erythropoietin levels of less than or equal to 500 milliunits per milliliter (mUnits/mL).

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.

To reduce the need for allogeneic RBC transfusions among patients with perioperative hemoglobin greater than 10 to less than or equal to 13 grams per deciliter (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.

Compendial Uses

- Symptomatic anemia in patients with myelodysplastic syndromes (MDS)[4,5,13,14,15]
- Anemia in patients who will not/cannot receive blood transfusions[5,6]
- Myelofibrosis-associated anemia[4,5,9]
- Cancer patients who are undergoing palliative treatment[4]

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

Coverage Criteria

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.

Anemia Due to Chronic Kidney Disease (CKD)[1-3,7]

Authorization of 12 weeks may be granted for treatment of anemia due to chronic kidney disease in members with pretreatment hemoglobin less than 10 g/dL.

Anemia Due to Myelosuppressive Chemotherapy[1-3,8]

Authorization of 12 weeks may be granted for treatment of anemia due to myelosuppressive chemotherapy in members with non-myeloid malignancy and pretreatment hemoglobin less than 10 g/dL.

Anemia in Myelodysplastic Syndrome (MDS)[4,5,8,12-13]

Authorization of 12 weeks may be granted for treatment of anemia in myelodysplastic syndrome in members with pretreatment hemoglobin less than 10 g/dL.

Reduction of Allogeneic Red Blood Cell Transfusion in Patients Undergoing Elective, Noncardiac, Nonvascular Surgery[1-3]

Authorization of 8 weeks may be granted for reduction of allogenic red blood cell transfusion in members scheduled to have an elective, noncardiac, nonvascular surgery with pretreatment hemoglobin less than or equal to 13 g/dL.

Anemia Due to Zidovudine in HIV-infected Patients[1-3]

Authorization of 12 months may be granted for treatment of anemia due to zidovudine in HIV-infected members currently receiving zidovudine with pretreatment hemoglobin less than 10 g/dL whose pretreatment serum EPO level is less than or equal to 500 mU/mL.

Anemia in Members Who Will Not/Cannot Receive Blood Transfusions[5]

Authorization of 12 weeks may be granted for treatment of anemia in members who will not/cannot receive blood transfusions (e.g., religious beliefs) with pretreatment hemoglobin less than 10 g/dL.

Myelofibrosis-associated Anemia[4,5,9,10]

Authorization of 12 weeks may be granted for treatment of myelofibrosis-associated anemia in members who meet both of the following criteria:

Pretreatment hemoglobin less than 10 g/dL.
Pretreatment serum EPO level less than 500 mU/mL.

Anemia Due to Cancer[4,8]

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

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 (excluding Anemia due to Zidovudine in HIV infected patients): All members (including new members) requesting authorization for continuation of therapy after at least 12 weeks of erythropoiesis-stimulating agent (ESA) treatment must show a response with a rise in hemoglobin of greater than or equal to 1 g/dL. Members who completed less than 12 weeks of ESA treatment and have not yet responded with a rise in hemoglobin of greater than or equal to 1 g/dL may be granted authorization of up to 12 weeks to allow for sufficient time to demonstrate a response.

Anemia Due to CKD[1-3,7]

Authorization of 12 weeks may be granted for continued treatment of anemia due to chronic kidney disease in members with current hemoglobin less than 12 g/dL.

Anemia Due to Myelosuppressive Chemotherapy[1-3,8]

Authorization of 12 weeks may be granted for the continued treatment of anemia due to myelosuppressive chemotherapy in members with non-myeloid malignancy and current hemoglobin less than 12 g/dL.

Anemia in Myelodysplastic Syndrome (MDS)[4,5,8,12,14]

Authorization of 12 weeks may be granted for continued treatment of anemia in myelodysplastic syndrome in members with current hemoglobin is less than 12 g/dL.

Reduction of Allogenic Red Blood Cell Transfusion in Patients Undergoing Elective, Noncardiac, Nonvascular Surgery[1-3]

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

Anemia Due to Zidovudine in HIV-infected Patients[1-3]

Authorization of 12 months may be granted for continued treatment of anemia due to zidovudine in HIV-infected members receiving zidovudine with current hemoglobin less than 12 g/dL.

Anemia in Members Who Will Not/Cannot Receive Blood Transfusions[5]

Authorization of 12 weeks may be granted for continued treatment of anemia in members who will not/cannot receive blood transfusions (e.g., religious beliefs) with current hemoglobin less than 12 g/dL.

Myelofibrosis-associated Anemia[4,5,9,10]

Authorization of 12 weeks may be granted for continued treatment of anemia in myelofibrosis-associated anemia with current hemoglobin less than 12 g/dL.

Anemia Due to Cancer[4]

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.

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SECTION 1

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SECTION 2

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