COMMON GROUND
HEALTHCARE COOPERATIVE

# PHARMACY POLICY STATEMENT
## Common Ground Healthcare Cooperative (CGHC)

| **DRUG NAME** | **Epoetin alfa (Epogen, Procrit, Retacrit)** |
|---|---|
| BILLING CODE | Epogen/Procrit: J0885 (non-ESRD)<br>Retacrit: Q5106 (non-ESRD)<br>Pharmacy: NDC |
| BENEFIT TYPE | Medical or Pharmacy |
| STATUS | Prior Authorization Required |

Epoetin alfa is an erythropoiesis-stimulating agent (ESA) indicated for: 1) Treatment of anemia due to a) chronic kidney disease (CKD) in patients on dialysis and not on dialysis, b) Zidovudine in patients with HIV-infection, c) the effects of concomitant myelosuppressive chemotherapy, or 2) Reduction of allogeneic red blood cell (RBC) transfusions in patients undergoing elective, noncardiac, nonvascular surgery. Retacrit (epoetin alfa-epbx) is a non-interchangeable biosimilar of the reference products Epogen and Procrit. Epoetin alfa stimulates erythropoiesis by the same mechanism as endogenous erythropoietin to stimulate RBC production.
ESAs are the standard of care for treating anemia in CKD (especially in dialysis patients), reducing the need for blood transfusions. Typically, increased hemoglobin levels are not observed earlier than 2 weeks after treatment initiation. A boxed warning states ESAs increase the risk of death, myocardial infarction, stroke, venous thromboembolism, thrombosis of vascular access, and tumor progression or recurrence. The lowest sufficient dose should be used.

Epoetin alfa will be considered for coverage when the following criteria are met:

## Anemia

For **initial** authorization:

1. Medication must be prescribed by or in consultation with hematologist/oncologist, nephrologist, immunologist, or infectious disease specialist; AND
2. Member meets one of the following:
   a) At least 1 month of age with a diagnosis of anemia due to chronic kidney disease (CKD)
   b) At least 8 months of age with a diagnosis of anemia due to zidovudine being used at a dose of 4200 mg/week or less to treat HIV with an endogenous serum erythropoietin level of ≤ 500 mUnits/mL; AND
3. Member's labs show adequate iron stores with both of the following:
   a) Transferrin saturation is at least 20%
   b) Ferritin is at least 100 mcg/L; AND
4. Member's labs show hemoglobin ≤10 g/dL within the last 30 days; AND
5. Member does NOT have uncontrolled hypertension.
6. **Dosage allowed/Quantity limit:** Recommended starting doses--
   Adults with CKD: 50 to 100 units/kg 3 times weekly IV or subQ
   Pediatrics with CKD (1 month to 18 years of age): 50 units/kg 3 times weekly IV or subQ
   HIV patients on zidovudine (adults): 100 units/kg IV or subQ 3 times per week
   HIV patients on zidovudine (pediatrics 8 months and older—OFF LABEL): 50 to 400 units/kg IV or subQ, 2 to 3 times per week

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HEALTHCARE COOPERATIVE

***If all the above requirements are met, the medication will be approved for 6 months.***

For **reauthorization**:
1. Labs must show stabilized or increased hemoglobin level compared to baseline, not to exceed 11.5 g/dL (12 g/dL for pediatrics or zidovudine patients); AND
2. Red blood cell transfusions are not required or the number of transfusions has decreased compared to baseline; AND
3. Member has adequate iron stores or is on iron therapy; AND
4. Member has not developed pure red cell aplasia (PRCA).

***If all the above requirements are met, the medication will be approved for an additional 6 months.***

## Surgery

For **initial** authorization:
1. Member is at least 18 years of age; AND
2. Epoetin is being prescribed to reduce allogeneic RBC transfusions in a member undergoing elective, noncardiac, nonvascular surgery; AND
3. Member is at high risk for perioperative blood loss; AND
4. Member's perioperative hemoglobin level is from 10 to 13 g/dL; AND
5. Member's labs show adequate iron stores with both of the following:
   a) Transferrin saturation is at least 20%
   b) Ferritin is at least 100 mcg/L; AND
6. Member does NOT have uncontrolled hypertension.
7. **Dosage allowed/Quantity limit:** 300 Units/kg per day subcutaneously 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/kg subcutaneously in 4 doses administered 21, 14, and 7 days before surgery and on the day of surgery.

***If all the above requirements are met, the medication will be approved for 30 days.***

For **reauthorization**:
1. Epoetin will not be reauthorized for this indication.

## Anemia Due to Chemotherapy in Patients with Cancer

Any request for cancer must be submitted through NantHealth/Eviti portal.

## Common Ground Healthcare Cooperative (CGHC) considers epoetin alfa not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

| DATE | ACTION/DESCRIPTION |
|---|---|
| **09/28/2022** | New policy for epoetin alfa created; combined policies for Epogen, Procrit, Retacrit. |

References:


1. Epogen [prescribing information]. Amgen Inc.; 2018.
2. Procrit [prescribing information]. Amgen Inc.; 2018.
3. Retacrit [prescribing information]. Hospira, Inc., a Pfizer Company; 2020.

4. Singh AK, Szczech L, Tang KL, et al. Correction of anemia with epoetin alfa in chronic kidney disease. *N Engl J Med*. 2006;355(20):2085-2098. doi:10.1056/NEJMoa065485
5. Kliger AS, Foley RN, Goldfarb DS, et al. KDOQI US commentary on the 2012 KDIGO Clinical Practice Guideline for Anemia in CKD. *Am J Kidney Dis*. 2013;62(5):849-859. doi:10.1053/j.ajkd.2013.06.008
6. Palmer SC, Saglimbene V, Mavridis D, et al. Erythropoiesis-stimulating agents for anaemia in adults with chronic kidney disease: a network meta-analysis. *Cochrane Database Syst Rev*. 2014;2014(12):CD010590. Published 2014 Dec 8. doi:10.1002/14651858.CD010590.pub2

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