

| PHARMACY POLICY STATEMENT | |
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| North Carolina Marketplace | |
| DRUG NAME | Procrit (epoetin alfa) |
| BILLING CODE | For Medical - J0885 (Non-ESRD) |
| | For Pharmacy - Must use valid NDC code |
| BENEFIT TYPE | Medical or Pharmacy |
| SITE OF SERVICE ALLOWED | Office, Outpatient |
| COVERAGE REQUIREMENTS | Prior Authorization Required (Preferred Product) |
| | QUANTITY LIMIT— vary per diagnosis |
| LIST OF DIAGNOSES CONSIDERED NOT | Click Here |
| MEDICALLY NECESSARY | |

Procrit (epoetin alfa) is a **preferred** product and will only be considered for coverage under the **medical or pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

ANEMIA

For **initial** authorization:

- 1. Medication must be prescribed by an oncologist, a nephrologist, an immunologist or infectious disease specialist; AND
- 2. Member has documented diagnosis of anemia due to **one** of the following:
 - a) Myelodysplastic syndrome;
 - b) Chronic Kidney Disease (GFR below 60 mL/min/1.73 m2);
 - c) Concomitant Zidovudine treatment in member with HIV-infection;
 - d) The effects of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy; AND
- 3. Member's individual iron status reveals **both** of the following:
 - a) Transferrin saturation is at least 20%;
 - b) Ferritin is at least 100 mcg/L; AND
- 4. Member is on supplemental iron therapy (unless serum ferritin level > 800 mcg/L); AND
- 5. Member's labs show hemoglobin ≤10 g/dL for adults (≤11 g/dL for children) within the last 14 days for initial therapy, OR ≤10.5 g/dL for adults (≤11.5 g/dL for children) currently receiving therapy.
- 6. **Dosage allowed:** Members with CKD 50 to 100 Units/kg 3 times weekly (adults) as initial dose and 50 Units/kg 3 times weekly (pediatric patients). Individualize maintenance dose. Intravenous route recommended for members on hemodialysis. Members on Zidovudine due to HIV-infection -100 Units/kg 3 times weekly. Members with cancer 40,000 Units weekly or 150 Units/kg 3 times weekly (adults); 600 Units/kg intravenously weekly (pediatric patients ≥5 years).

If member meets all the requirements listed above, the medication will be approved for 6 months.



For reauthorization:

- 1. Member's hemoglobin increased, stayed the same and not decreased further (baseline labs and current labs required); AND
- 2. Red blood cells transfusions are not required or the number of the transfusions has decreased.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 6 months.

REDUCTION OF ALLOGENEIC RBC TRANSFUSIONS

For initial authorization:

- 1. Medication must be prescribed by an oncologist, a nephrologist, an immunologist or infectious disease specialist; AND
- 2. Medication is being used for reduction of allogeneic RBC transfusions in member undergoing elective, non-cardiac, nonvascular high-risk surgery at increased risk of or intolerant to transfusions; AND
- Member's labs show hemoglobin ≤13 g/dL.
- 4. **Dosage allowed:** 300 Units/kg per day daily for 15 days or 600 Units/kg weekly.

If member meets all the requirements listed above, the medication will be approved for 3 months. For reauthorization:

1. Medication will not be reauthorized.

CareSource considers Procrit (epoetin alfa) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- In members with cancer receiving hormonal agents, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy
- In members with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure
- In members with cancer receiving myelosuppressive chemotherapy in whom the anemia can be managed by transfusion
- In members scheduled for surgery who are willing to donate autologous blood
- In members undergoing cardiac or vascular surgery
- As a substitute for RBC transfusions in patients who require immediate correction of anemia

| DATE | ACTION/DESCRIPTION | |
|------------|---|--|
| 10/04/2018 | New policy for Procrit created. Hemoglobin requirement expanded. Endogenous serum | |
| | erythropoietin level requirement removed. | |

References:

- 1. Procrit [package insert]. Thousand Oaks, CA: Amgen; September, 2017.
- 2. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology; Cancer- and Chemotherapy- Induced Anemia. V.2.2018. Available at https://www.nccn.org/professionals/physician_gls/pdf/anemia.pdf. Accessed January 30, 2018.
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- 4. Young. D. CMS Anemia Drugs Proposal: Bad for Amgen, Good for Patients, 17 May 2007.

Qualified Health Plans offered in North Carolina by CareSource North Carolina Co., d/b/a CareSource.



- 5. New risk management program for erythropoiesis-stimulating agents. Aranesp, Procrit, and Epogen Article; Pharmacist's Letter; April 2010; Vol: 26 Hematology / Oncology.
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- 8. Pediatr AIDS and HIV Infect: Fetus to Adolesc. 1994;5:169-173.
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- 11. Glaspy J, Crawford J, Vansteenkiste J, Henry D, Rao S, Bowers P, Berlin JA, Tomita D, Bridges K, Ludwig H Br J Cancer. 2010;102(2):301. American Society of Clinical Oncology/American Society of Hematology clinical practice guideline update on the use of epoetin and darbepoetin in adult patients with cancer.
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- 13. Aliment Pharmacol Ther. 2010 May;31(9):929-37. Epub 2010 Feb 18.Review article: optimizing SVR and management of the haematological side effects of peginterferon/ribavirin antiviral therapy for HCV the role of epoetin, G-CSF and novel agents.
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Effective date: 01/01/2023 Revised date: 10/04/2018