

PHARMACY POLICY STATEMENT

Indiana Medicaid

DRUG NAME	Retacrit (epoetin alfa-epbx)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home/Office
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) Alternative preferred product includes Aranesp QUANTITY LIMIT— see Dosage allowed below
LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY	Click Here

Retacrit (epoetin alfa-epbx) is a **non-preferred** product and will only be considered for coverage under the **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; 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
3. Member's labs show hemoglobin \leq 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 Retacrit (epoetin alfa-epbx) 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
10/11/2019	New policy for Retacrit created.

References:

1. Retacrit [prescribing information]. New York, NY: Pfizer Inc.; January 2019.

Effective date: 04/01/2020

Revised date: 10/11/2019