Pharmacy Medical Necessity Guidelines: Erythropoiesis Stimulating Agents (Aranesp®, Epogen®, Procrit®, Retacrit®)

Effective: January 1, 2021

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	MED/ RX	Department to Review	RxUM/ MM

These pharmacy medical necessity guidelines apply to the following:

Commercial Products

☐ Tufts Health Plan Commercial products – large group plans
☐ Tufts Health Plan Commercial products – small group and individual plans
☐ Tufts Health Freedom Plan products – large group plans
☐ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:
Pharmacy Benefit Utilization:
RXUM: 617.673.0988

Medical Benefit Utilization
MM: 888.415.9055

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMISTRATION (FDA)-APPROVED INDICATIONS

- **Anemia Due to Chronic Kidney Disease (CKD)**
  - Aranesp, Epogen, Procrit: Is indicated for the treatment of anemia due to CKD, including patients on dialysis and patients not on dialysis
- **Anemia Due to Chemotherapy in Patients with Cancer**
  - Aranesp, Epogen, Procrit: Is indicated for the 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
- **Anemia Due to Zidovudine in Patients with HIV-infection**
  - Epogen, Procrit: Is indicated for the treatment of anemia due to zidovudine administered at ≤4,200 mg/week in patients with HIV-infection with endogenous serum erythropoietin levels of ≤500 mUnits/mL
- **Reduction of Allogenic Red Blood Cell Transfusions in Patients Undergoing Elective, Noncardiac, Nonvascular Surgery**
  - Epogen, Procrit: Is indicated to reduce the need for allogenic RBC transfusions among patients with perioperative hemoglobin >10 to ≤13 g/dL who are at high risk for perioperative blood loss from elective, noncardiac, nonvascular surgery.

A biosimilar is a biological product (developed from living cells) developed to be similar to an already FDA-approved biologic (or reference product). A biosimilar may have different indications than the reference product. A biosimilar is not an exact duplicate of the reference product; therefore, not considered a generic product. However, there are no clinically meaningful differences between a biosimilar and reference product in terms of safety and efficacy.

COVERAGE GUIDELINES

The plan may authorize coverage of Aranesp, Epogen, Procrit, and Retacrit for Members, when the following criteria are met:

Anemia due to chronic renal failure

1. Documented diagnosis anemia due to chronic renal failure

AND

2. Documentation of **one (1)** of the following:
   a. Adult member with a hemoglobin level <10 g/dL within the last 60 days
   b. Pediatric member who is symptomatic and hemoglobin level <11 g/dL within the last 60 days

AND

3. Documentation of **one (1)** of the following:
    a. Glomerular filtration rate (GFR) ≤30 mL/min
    b. Glomerular filtration rate (GFR) 30-60 mL/min noting that other causes of anemia have been ruled out (e.g., iron, vitamin B12, folate deficiency and hemolysis)

Anemia due to post-renal transplant, chemotherapy treatment for cancer, and idiopathic sideroblastic anemia/myelodysplastic syndrome

1. Documented diagnosis of **one (1)** of the following:
    a. Anemia due to post-renal failure
    b. Anemia due to chemotherapy treatment for cancer
    c. Anemia due to idiopathic sideroblastic anemia/myelodysplastic syndrome

AND

2. Documentation of **one (1)** of the following:
    a. Adult member with a hemoglobin level <10 g/dL within the last 60 days
    b. Pediatric member who is symptomatic and hemoglobin level <11 g/dL within the last 60 days

Anemia due to myelosuppressive medication regimen for HIV

1. Documented diagnosis of anemia due to myelosuppressive medication regimen for HIV

AND

2. Documentation of **one (1)** of the following:
    a. HIV medication regimen includes zidovudine or zidovudine-containing products
    b. All other causes of anemia have been ruled out (e.g., iron, vitamin B12, folate deficiency, and hemolysis

AND

3. Documentation of **one (1)** of the following:
    a. Adult member with a hemoglobin level <10 g/dL within the last 60 days
    b. Pediatric member who is symptomatic and hemoglobin level <11 g/dL within the last 60 days

Anemia due to myelosuppressive medication regimen for Hepatitis C

1. Documented diagnosis of anemia due to myelosuppressive medication regimen for Hepatitis C

AND

2. Documentation of **one (1)** of the following:
    a. Adult member with a hemoglobin level <10 g/dL within the last 60 days
    b. Pediatric member who is symptomatic and hemoglobin level <11 g/dL within the last 60 days

AND

3. Documentation of **one (1)** of the following:
    a. Member is currently being treated with hepatitis C regimen containing an interferon product
    b. Member is currently being treated with a hepatitis C regimen containing ribavirin with no interferon product AND the provider documents that a ribavirin dose reduction to 600 mg/day has previously been attempted

Decrease need for blood transfusion in surgery patients

1. Documented use to decrease the need for blood transfusion in a surgery patient

AND

2. Documentation the Member has a hemoglobin level <13 g/dL within the last 30 days

AND

3. Documentation the Member is scheduled to undergo surgery within the next three (3) months

LIMITATIONS

1. Member's receiving hemodialysis do not require prior authorization for any erythropoiesis stimulating agent since the medication is provided by the clinic.

CODES

The following HCPCS/CPT code(s) are:

Code	Description
J0881	Injection, darbepoetin alfa, 1 microgram (non-ESRD use)

Code	Description
J0885	Injection, epoetin alfa, (non-ESRD use), 1000 units
Q5106	Injection, epoetin afla-epbx, biosimilar (retacrit) (for non-esrd use), 1000 units

REFERENCES

1. Aranesp (darbepoetin alfa) [prescribing information]. Thousand Oaks, CA: Amgen Inc.; January 2019.
2. Epogen (epoetin alfa) [prescribing information]. Thousand Oaks, CA: Amgen Inc.; July 2018.
3. Procrit (epoetin alfa) [prescribing information]. Thousand Oaks, CA: Amgen Inc.; July 2018.
4. Retacrit (epoetin alfa-epbx) [prescribing information]. Lake Forest, IL: Pfizer Company; June 2020.

APPROVAL HISTORY

November 24, 2020: Reviewed by Pharmacy & Therapeutics Committee for an effective date of January 1, 2020 for implementation of MassHealth ACPP/MCO Partial Unified Formulary.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.