Generic Name: N/A

Therapeutic Class or Brand Name:
Erythropoiesis-Stimulating Agents (ESAs)

Applicable Drugs (if Therapeutic Class):
Aranesp® (darbepoetin alfa), Epogen® (epoetin alfa), Procrit® (epoetin alfa), Mircera® (methoxy polyethylene glycol-epoetin beta), Retacrit® (epoetin alfa-epbx).

Preferred: Retacrit® (epoetin alfa-epbx)

Non-preferred: Aranesp® (darbepoetin alfa), Epogen® (epoetin alfa), Mircera® (methoxy polyethylene glycol-epoetin beta), Procrit® (epoetin alfa)

Date of Origin: 2/1/2013

Date Last Reviewed / Revised: 11/18/2024

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through IV are met)

I. Documented diagnosis of one of the following conditions A through D AND must meet criteria listed under applicable diagnosis:

A. Anemia due to Chronic Kidney Disease (CKD) in patients on dialysis and patients not on dialysis:

1. Current hemoglobin is less than 10 g/dL.
2. For Mircera: patients are converting from another ESA after their hemoglobin was stabilized with an ESA.
3. Minimum age requirement:
    a. Aranesp, Retacrit, Epogen, and Procrit: 1 month old.
    b. Mircera: 3 months old.

B. Anemia due to Zidovudine in HIV-infected patients:

1. Current hemoglobin is less than 10 g/dL.
2. Minimum age requirement:
    a. Retacrit, Epogen and Procrit: 8 months old.

C. Anemia due to the effects of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy:

    a. Retacrit, Epogen, and Procrit: 5 years old.
    b. Aranesp: 18 years old.

D. Reduction of allogeneic RBC transfusions in patients undergoing elective, nonvascular, or noncardiac surgery:

1. Perioperative hemoglobin between 10 and 13 g/dL.
2. Expecting to require at least 2 units of blood.

3. Minimum age requirement:
    a. Retacrit, Epogen, and Procrit: 18 years old.

II. Treatment must be prescribed by or in consultation with a hematologist, oncologist, nephrologist, gastroenterologist, or infectious disease specialist.

III. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

IV. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- Patients with active gastrointestinal bleeding.
- Patients with cancer receiving hormonal agents, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy.
- Patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure.
- Patients with cancer receiving myelosuppressive chemotherapy when the anemia can be managed by transfusion.
- Patients scheduled for surgery who are willing to donate autologous blood.
- Patients undergoing cardiac or vascular surgery.
- As a substitute for RBC transfusions in patients who require immediate correction of anemia.
- Patients with uncontrolled hypertension.
- Patients with Pure Red Cell Aplasia (PRCA) that begins after treatment with erythropoietin protein drugs.
- Aranesp is not indicated for the treatment of anemia due to cancer chemotherapy in pediatric patients.
- Aranesp and Mircera are not indicated for the treatment of anemia due to Zidovudine therapy in HIV patients or for reduction of allogeneic red blood cell (RBC) transfusions in patients undergoing surgery.
- Mircera is not indicated for treatment of anemia due to cancer chemotherapy.

OTHER CRITERIA

- Pregnant women, lactating women, neonates and infants: use only Retacrit, Epogen, and Procrit single-dose vials (multi-dose vials containing benzyl alcohol preservatives are contraindicated).

QUANTITY / DAYS SUPPLY RESTRICTIONS

- The quantity is limited to a maximum of a 30-day supply per fill.

APPROVAL LENGTH

- **Authorization:**
  - Surgery: One time approval only.
  - All other indications: 6 months.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing improvement or maintenance with medication, including no GI bleeding and hemoglobin less than 11 g/dL.

APPENDIX

N/A

REFERENCES

1. Epogen. Prescribing Information. Amgen Inc; 2024. Accessed October 21, 2024. http://pi.amgen.com/united_states/epogen/epogen_pi_hcp_english.pdf.
2. Procrit. Prescribing Information. Janssen Products; 2024. Accessed October 21, 2024. https://www.dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=0c721ba4-ae19-417f-aae1-221ed1a0866a.
3. Retacrit. Prescribing Information. Pfizer Inc; 2024. Accessed October 21, 2024. http://labeling.pfizer.com/ShowLabeling.aspx?id=10738.
4. Aranesp. Prescribing Information. Amgen Inc; 2024. Accessed October 21, 2024. http://pi.amgen.com/united_states/aranesp/ckd/aranesp_pi_hcp_english.pdf.
5. Mircera. Prescribing Information. Vifor (International) Inc; 2024. Accessed October 21, 2024. https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=22c56f2a-f73c-60e7-e054-00144ff88e88#drug-information