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: 2/14/2023

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through V 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 in patients on dialysis and patients not on dialysis, and medication specific criterion 1 through 3 is met:

      1. For Retacrit™, Epogen®, Procrit®: minimum age requirement is 1 month old.
      2. For Aranesp®: minimum age requirement is 1 year old.
      3. For Mircera®: minimum age 18 years old or pediatric patients 5 to 7 years of age on hemodialysis who are converting from another ESA after their hemoglobin level was stabilized with an ESA.

   B. Anemia due to Zidovudine in HIV-infected patients and criterion 1 is met:

      1. For Retacrit™, Epogen® and Procrit®: minimum age requirement is 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, and criterion 1 is met:

      1. For Retacrit™, Epogen®, Procrit®: minimum age requirement: 5 years old.
      2. For Aranesp®: minimum age requirement is 18 years old.

   D. Reduction of allogeneic RBC transfusions in patients undergoing elective, nonvascular, noncardiac surgery and criterion 1 is met (Retacrit™, Epogen® or Procrit®: approve one time only):

      1. For Retacrit™, Epogen® and Procrit®: minimum age requirement is 18 years old.

II. Prescribed by or in consultation with a hematologist, oncologist, nephrologist, gastroenterologist, or infectious disease specialist.

III. Documentation showing that the patient does not have any GI bleeding.

IV. Documentation that current hemoglobin is less than 10 g/dL.

V. Non-preferred products require a documented failure, intolerance, or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- 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.
- Mircera may be given intravenously or subcutaneously in adult patients and only intravenously in pediatric patients.

OTHER CRITERIA

- Pregnant women, lactating women, neonates and infants: use only Epogen®, Retacrit®, and Procrit® single-dose vials (Epogen®, Retacrit®, and Procrit® 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:** 6 months (unless otherwise stated under Prior Authorization Criteria section).
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing no GI bleeding and hemoglobin less than 11 g/dL.

APPENDIX

N/A

REFERENCES

1. Aranesp®. Prescribing information. Thousand Oaks, CA; Amgen. January 2019. Accessed February 14, 2023. https://www.pi.amgen.com/-/media/Project/Amgen/Repository/pi-amgen-com/aranesp/ckd/aranesp_pi_hcp_english.pdf.
2. Epogen®. Prescribing information. Thousand Oaks, CA; Amgen. July 2018. Accessed February 14, 2023. https://www.pi.amgen.com/-/media/Project/Amgen/Repository/pi-amgen-com/Epogen/epogen_pi_hcp_english.pdf.
3. Mircera®. Prescribing information. St. Gallen, Switzerland; Vifor. June 2018. Accessed February 14, 2023. https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/125164s078lbl.pdf.
4. Retacrit®. Prescribing information. Lake Forest, IL; Pfizer. August 2020. Accessed February 14, 2023. https://labeling.pfizer.com/ShowLabeling.aspx?id=10738#S2.2.
5. Procrit®. Prescribing information. Thousand Oakes, CA; Janssen. July 2018. Accessed February, 14, 2023. https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/PROCRIT-pi.pdf.