

New Hampshire Medicaid Fee-for-Service Program Hematopoietic Agent Criteria

Approval Date: January 26, 2023

Pharmacology

Erythropoietin is a glycoprotein that stimulates red blood cell production. It is produced in the kidney and stimulates the division and differentiation of committed erythroid progenitors in the bone marrow.

Indications

- Procrit[®], Epogen[®] and Retacrit[®] are indicated in the treatment of anemia of chronic renal failure, zidovudine-treated HIV-infected patients, anemia in cancer patients on chemotherapy, and reduction of allogeneic blood transfusions in surgery patients.
- Aranesp[®] is indicated in the treatment of anemia associated with chronic renal failure, including patients on dialysis and not on dialysis, and for the treatment of anemia in patients with nonmyeloid malignancies where anemia is due to the effect of concomitantly administered chemotherapy.
- Mircera[®] is indicated for the treatment of anemia associated with chronic kidney disease (CKD) in adult patients on dialysis and patients not on dialysis.

Medications

| Brand Names | Generic Names | Dosage |
|----------------------|------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Aranesp [®] | darbepoetin alfa | vial: 25 mcg/mL, 40 mcg/mL, 60 mcg/mL, 100 mcg/mL, 200 mcg/mL syringe: 10 mcg/0.4 mL, 25 mcg/0.42 mL, 40 mcg/0.4 mL, 60 mcg/0.3 mL, 100 mcg/0.5 mL, 150 mcg/0.3 mL, 200 mcg/0.4 mL, 300 mcg/0.6 mL, 500 mcg/1 mL |
| Epogen [®] | epoetin alfa | 2,000 U/mL, 3,000 U/mL, 4,000 U/mL, 10,000 U/mL, 20,000 U/mL, 20,000 U/2 mL |
| Procrit [®] | epoetin alfa | 2,000 U/mL, 3,000 U/mL, 4,000 U/mL, 10,000 U/mL, 20,000 U/mL, 20,000 U/2 mL, 40,000 U/mL |
| Mircera [®] | methoxy polyethylene glycol-epoetin beta | 30 mcg/0.3 mL, 50 mcg/0.3 mL, 75 mcg/0.3 mL, 100 mcg/0.3 mL, 150 mcg/0.3 mL, 200 mcg/0.3 mL |

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| Brand Names | Generic Names | Dosage |
|-------------|-------------------|-----------------------------------------------------------------------------------------------|
| Retacrit® | epoetin alfa-epbx | 2,000 U/ mL, 3,000 U/ mL, 4,000 U/ mL, 10,000 U/ mL, 20,000 U/ mL, 20,000 U/2 mL, 40,000 U/mL |

Criteria for Approval

1. A documented HCT <30%; **AND**
2. A documented hemoglobin (Hb) < 10 g/dL; **AND**
3. Iron levels performed (transferrin saturation \geq 20%, ferritin \geq 100 ng/mL); **AND**
4. Lab data within two months of prior authorization (PA) submission; **AND**
5. One of the following diagnoses:
 - a. Anemia associated with chronic kidney disease, predialysis, or on dialysis (this is the only diagnosis that can be approved for Mircera®); **OR**
 - b. Anemia associated with cancer chemotherapy; **OR**
 - c. Anemia in cancer patients who are not treated with chemotherapy but have anemia associated with any of the following: prior chemotherapy, prior radiation therapy, current treatment with radiation therapy, or malignancy; **OR**
 - d. Anemia in patients with HIV who are receiving zidovudine therapy (Procrit®, Epogen®, or Retacrit® only); **OR**
 - e. Reduction of allogeneic blood transfusions in surgery patients (Procrit®, Epogen®, or Retacrit® only); **OR**
 - f. Anemia in myelodysplastic syndromes (MDS); **OR**
 - g. Anemia in lymphoproliferative disease; **OR**
 - h. Anemia due to ribavirin use in patients infected with hepatitis C.

Length of Approval: 6 months

Criteria for Denial

1. Criteria for approval not met; **OR**
2. A documented HCT > 36%; **AND**
3. A documented Hb > 12 g/dL; **OR**
4. One of the following diagnoses:
 - a. Pruritis (uremic); **OR**
 - b. Patients requiring immediate correction of severe anemia; **OR**
 - c. Anemia in patients with rheumatoid arthritis; **OR**

- d. Anemia of prematurity; **OR**
- e. Anemia in women with postpartum iron deficiency anemia; **OR**
- f. Sickle-cell anemia in patients who do not respond to hydroxyurea; **OR**
- g. Patients with cancer receiving hormonal agents, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy or in whom anemia can be managed by transfusion (Procrit[®], Epogen[®], Aranesp[®] or Retacrit[®] only); **OR**
- h. Anemia due to cancer chemotherapy (Mircera[®] only).

Criteria for Denial of a Renewal

- 1. Appropriate dose increase did not produce >1 g/dL in Hb; **OR**
- 2. A documented HCT > 36%; **AND**
- 3. A documented Hb > 2 g/dL.

References

Available upon request.

Revision History

| Reviewed by | Reason for Review | Date Approved |
|----------------------------------|-------------------|---------------|
| Pharmacy & Therapeutic Committee | New | 11/02/2006 |
| Commissioner | New | 11/16/2006 |
| Pharmacy & Therapeutic Committee | Revision | 06/19/2008 |
| Commissioner | Approval | 07/22/2008 |
| DUR Board | Revision | 10/25/2010 |
| Commissioner | Approval | 02/10/2011 |
| DUR Board | Revision | 05/31/2016 |
| Commissioner | Approval | 06/18/2016 |
| DUR Board | Revision | 09/27/2018 |
| Commissioner Designee | Approval | 11/27/2018 |
| DUR Board | Revision | 03/12/2019 |
| Commissioner Designee | Approval | 04/05/2019 |
| DUR Board | Revision | 06/30/2020 |
| Commissioner Designee | Approval | 08/07/2020 |
| DUR Board | Revision | 06/08/2021 |
| Commissioner Designee | Approval | 08/13/2021 |

| Reviewed by | Reason for Review | Date Approved |
|-----------------------|-------------------|---------------|
| DUR Board | Revision | 12/13/2022 |
| Commissioner Designee | Approval | 01/26/2023 |