Pharmacy Medical Necessity Guidelines:

# Hematinic Agents: Aranesp (darbepoetin afla), Epogen (epoetin alfa), Procrit (epoetin alfa), Retacrit (epoetin alfa-epbx), Mircera (methoxy peg-epoetin beta)

*Effective: July 14, 2026*

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| **Guideline Type** | ☒ Prior Authorization<br>☐ Non-Formulary<br>☐ Step-Therapy<br>☐ Administrative |

**Applies to:**

**Commercial Products**

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

**Public Plans Products**

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

**Note:** While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

## Overview

**Food and Drug Administration – Approved Indications**

**Aranesp** (darbepoetin afla) is an erythropoiesis-stimulating agent indicated for the treatment of anemia due to chronic kidney disease in patients on dialysis and patients not on dialysis, and the effects of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy.

Aranesp has not been shown to improve quality of life, fatigue, or patient well-being. Aranesp is not indicated for use in patients with cancer receiving hormonal agents, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy; in patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure; in patients with cancer receiving myelosuppressive chemotherapy in whom the anemia can be managed by transfusion; or as a substitute for red blood cell transfusions in patients who require immediate correction of anemia.

**Epoetin alfa** (Epogen, Procrit, Retacrit) is an erythropoiesis-stimulating agent indicated for the treatment of anemia due to chronic kidney disease in patients on dialysis and patients not on dialysis; zidovudine in patients with HIV-infection; and the effects of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy. Epoetin alfa is also indicated for the reduction of allogeneic red blood cell transfusions in patients undergoing elective, noncardiac, nonvascular surgery.

Epoetin alfa has not been shown to improve quality of life, fatigue, or patient well-being. Epoetin alfa is not indicated for use in patients with cancer receiving hormonal agents, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy; in patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure; in patients with cancer receiving myelosuppressive chemotherapy in whom the anemia can be managed by transfusion; in patients scheduled for surgery who are willing to donate autologous blood; in patients undergoing cardiac or vascular surgery; or as a substitute for red blood cell transfusions in patients who require immediate correction of anemia.

**Mircera** (methoxy polyethylene glycol-epoetin beta) is indicated for the treatment of anemia associated with chronic kidney disease in adult patients on dialysis and adult patient not on dialysis, and pediatric patients 3 months to 17 years of age on dialysis or not on dialysis who are converting from another ESA after their hemoglobin level was stabilized with an erythropoiesis-stimulating agent.

Mircera is not indicated and is not recommended in the treatment of anemia due to cancer chemotherapy and as a substitute for red blood cell transfusions in patients who require immediate correction of anemia. Mircera has not been shown to improve symptoms, physical functioning, or health-related quality of life.

## Clinical Guideline Coverage Criteria

### Aranesp

The plan may authorize coverage of Aranesp for Members when **ALL** of the following criteria are met:

1. Documentation of **one (1)** of the following:
    a. All of the following:
        i. Prescribed for the treatment of anemia due to chronic kidney disease, in a patient whose religious beliefs forbid blood transfusions, or due to cancer in a patient receiving palliative treatment
        ii. Patient has a documented pre-treatment hemoglobin level less than 10 g/dL
        iii. Adequate iron stores (a serum transferrin saturation greater than or equal to 20% within the prior three months or currently receiving iron therapy

        **OR**

    b. All of the following:
        i. Prescribed for the treatment of anemia due to primary myelofibrosis, post-polycythemia vera myelofibrosis, post essential thrombocytopenia myelofibrosis, or myelodysplastic syndrome
        ii. Pre-treatment serum erythropoietin level less than 500 mU/mL
        iii. Patient has a documented pre-treatment hemoglobin level less than 10 g/dL
        iv. Adequate iron stores (a serum transferrin saturation greater than or equal to 20% within the prior three months or currently receiving iron therapy

        **OR**

    c. Both of the following:
        i. Prescribed for the treatment of anemia due to a malignancy
        ii. Adequate iron stores (a serum transferrin saturation greater than or equal to 20% within the prior three months or currently receiving iron therapy

### Epogen, Procrit, and Retacrit

The plan may authorize coverage of Epogen, Procrit, or Retacrit for Members when **ALL** of the following criteria are met:

1. Documentation of **one (1)** of the following:
    a. All of the following:
        i. Prescribed for the treatment of anemia due to chronic kidney disease; rheumatoid arthritis; hepatitis C treatment and the patient is receiving ribavirin in combination with either interferon alfa or peginterferon alfa; zidovudine in HIV-infected patients with a pre-treatment serum erythropoietin level less than 500 mU/mL; in a patient whose religious beliefs forbid blood transfusions; or due to cancer in a patient receiving palliative therapy
        ii. Patient has a pre-treatment hemoglobin less than 10 g/dL
        iii. Adequate iron stores (a serum transferrin saturation greater than or equal to 20% within the prior three months or currently receiving iron therapy

        **OR**

    b. All of the following:
        i. Prescribed for the treatment of anemia due to primary myelofibrosis, post-polycythemia vera myelofibrosis, post essential thrombocytopenia myelofibrosis, or myelodysplastic syndrome
        ii. Pre-treatment serum erythropoietin level less than 500 mU/mL
        iii. Patient has a documented pre-treatment hemoglobin level less than 10 g/dL
        iv. Adequate iron stores (a serum transferrin saturation greater than or equal to 20% within the prior three months or currently receiving iron therapy

        **OR**

    c. Both of the following:
        i. Prescribed for the treatment of anemia due to congestive heart failure with pre-treatment hemoglobin levels less than 9 g/dL
        ii. Adequate iron stores (a serum transferrin saturation greater than or equal to 20% within the prior three months or currently receiving iron therapy

        **OR**

    d. Both of the following:
        i. Prescribed for the treatment of reduction of allogeneic red blood cell transfusion in a patient undergoing elective, non-cardiac, nonvascular surgery with a pre-treatment hemoglobin less than 13 g/dL
        ii. Adequate iron stores (a serum transferrin saturation greater than or equal to 20% within the prior three months or currently receiving iron therapy

        **OR**

e. Both of the following:
    i. Prescribed for the treatment of anemia due to a malignancy
    ii. Adequate iron stores (a serum transferrin saturation greater than or equal to 20% within the prior three months or currently receiving iron therapy

**Mircera**

The plan may authorize coverage of Mircera for Members when **ALL** of the following criteria are met:

1. Prescribed for the treatment of anemia due to chronic kidney disease in a patient with a pre-treatment hemoglobin level less than 10 g/dL

**AND**

2. Adequate iron stores (a serum transferrin saturation greater than or equal to 20% within the prior three months or currently receiving iron therapy

## Limitations

1. For a non-formulary medication request, please refer to the Pharmacy Medical Necessity Guidelines for Formulary Exceptions and submit a formulary exception request to the plan as indicated.

## Codes

None

## References


1. Aranesp [package insert]. Thousand Oaks, CA: Amgen Inc. December 2024.
2. Epogen [package insert]. Thousand Oaks, CA: Amgen Inc. December 2024.
3. Mircera [package insert]. Vifor (International) Inc. St. Gallen, Switzerland. April 2024.
4. Procrit [package insert]. Horsham, PA: Janssen Products. April 2024.
5. Retacrit [package insert]. Lake Forest, IL: Hospira Inc; June 2024.
6. National Comprehensive Cancer Network. The NCCN Drugs & Biologics Compendium. http://www.nccn.org. Accessed June 2024.
7. Rizzo JD, Brouwers M, Hurley P, et al. American Society of Clinical Oncology/American Society of Hematology clinical practice guideline update on the use of epoetin and darbepoetin in adult patients with cancer. J Clin Oncol. 2010;28(33):4996-5010.
8. Qaseem A, Humphrey LL, Fitterman N, Starkey M, Shekelle P, for the Clinical Guidelines Committee of the American College of Physicians. Treatment of Anemia in Patients with Heart Disease: A Clinical Practice Guideline from the American College of Physicians. Ann Intern Med. 2013;159:770-779.
9. Cervantes F, Alvarez-Larran A, Hernandez-Boluda JC, et al. Erythropoietin treatment of the anemia of myelofibrosis with myeloid metaplasia: results in 20 patients and review of the literature. Br J Haematol. 2004;127(4):399-403.


## Approval And Revision History

September 13, 2022: Reviewed by the Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- July 11, 2023: No changes
- July 9, 2024: No changes (eff 7/9/24)
- July 8, 2025: No changes. (eff 7/8/25)
- July 14, 2026: Administrative update to overview with Mircera’s expanded indication in pediatric patients. Administrative update to remove CareLink from the Medical Necessity Guideline template. (eff 7/14/26)

## 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.