Medical Necessity Guidelines
Medical Benefit Drugs

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

Effective: July 14, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ 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

☐ Tufts Health Together – MassHealth Accountable Care Partnership Plans; Fax 617-673-0939

☐ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939

☐ Tufts Health One Care* – A Medicare-Medicaid Plan (a dual eligible product); Fax 617-673-0956

*The MNG applies to Tufts Health One Care members unless a less restrictive LCD or NCD exists.

Senior Products

☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956

☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956

☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

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 erythropoiesis-stimulating agent (ESA) after their hemoglobin level was stabilized with an ESA. 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

ii. Documentation of a pre-treatment hemoglobin levels less than 9 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

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
   ii. Documentation of a pre-treatment hemoglobin less than 13 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

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

AND

2. Documentation of a pre-treatment hemoglobin level less than 10 g/dL

AND

3. Documentation of adequate iron stores (a serum transferrin saturation greater than or equal to 20% within the prior three months or currently receiving iron therapy)

Limitations

- None

Codes

The following HCPCS code(s) are:

Table 1: HCPCS Codes

HCPCS Codes	Description
J0881	Injection, darbepoetin alfa, 1 microgram (non-ESRD use)
J0885	Injection, epoetin alfa, (non-ESRD use), 1000 units
J0888	Injection, epoetin beta, 1 microgram, (for non esrd use)
Q5106	Injection, epoetin afla-epbx, biosimilar (Retacrit) (for non-esrd use), 1000 units

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. Kidney Disease: Improving Global Outcomes (KDIGO) Anemia Work Group. KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease. Kidney Int. 2012;Suppl 2:279-335.
7. National Kidney Foundation. KDOQI Clinical Practice Guideline and Clinical Practice Recommendations for Anemia in Chronic Kidney Disease: 2007 Update of Hemoglobin Target. http://www2.kidney.org/professionals/KDOQI/guidelines_anemiaUP/. Accessed September 19, 2018.
8. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Cancer- and Chemotherapy-Induced Anemia. Version 3.2018. http://www.nccn.org/professionals/physician_gls/pdf/anemia.pdf. Accessed September 19, 2018.
9. Ngo K, Kotecha D, Walters JAE, Manzano L, Palazzuoli A, van Veldhuisen DJ, Flather M. Erythropoiesis-stimulating agents for anaemia in chronic heart failure patients. Cochrane Database of Systematic Reviews 2010, Issue 1. Art. No.: CD007613. DOI: 10.1002/14651858.CD007613.pub2.

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11. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Myelodysplastic Syndromes. Version 3.2023. Accessed November 2023.
12. 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.
13. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Myeloproliferative Neoplasms. Version 3.2023.Accessed November 2023.
14. 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 Pharmacy and Therapeutics Committee (P&T)

September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC)

Subsequent endorsement date(s) and changes made:

- December 12, 2023: Removed reauthorization criteria throughout Medical Necessity Guideline. Added requirement for adequate iron sores throughout Medical Necessity Guidelines. For chronic kidney disease, removed pediatric requirements for pre-treatment hemoglobin and glomerular filtration rate requirements. Added additional approved uses for select erythropoiesis stimulating agents. Removed the Limitations Members receiving hemodialysis do not require prior authorization for any erythropoiesis stimulating agent since the medication is provided by the clinic, Initial Authorization will be granted for a period of up to 16 weeks if criteria are met, Reauthorizations will be granted for a period of up to 6 months if criteria are met, and Any indications other than those listed above are considered experimental or investigational and will not be approved by the health plan (effective March 1, 2024)
- December 2023: Administrative update to rebrand Tufts Heath Unify to Tufts Health One Care for 2024.
- October 8, 2024: No changes (eff 10/8/24)
- October 2024: Administrative Update: Updated Tufts Health Unify to Tufts Health One Care.
- July 2025: Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template.
- October 14, 2025: Administrative update to overview with Mircera's expanded age indication in pediatric patients 3 months to 17 years of age for the treatment of anemia associated with chronic kidney disease. (eff 10/14/25)
- July 14, 2026: Administrative updates: Template updated to remove CareLink from the Medical Necessity Guideline template. Template updated from "Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans" to "Tufts Health Together- MassHealth Accountable Care Partnership Plans."

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven 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 our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update 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 Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

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

Provider Services