

Erythropoiesis Stimulating Agents
Aranesp (darbepoetin alfa)
Epogen (epoetin alfa)
Procrit (epoetin alfa)
Effective 01/01/2026

Plan	<input checked="" type="checkbox"/> MassHealth UPPL <input type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization
Benefit	<input type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit		<input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Specialty Limitations	N/A		
Contact Information	Medical Benefit Pharmacy Benefit	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	Aranesp, Epogen, Procrit are also available on the pharmacy benefit. Please see the MassHealth Drug List for coverage and criteria.		

Overview

Aranesp, Epogen, Procrit and Retacrit are Erythropoiesis Stimulating Agents (ESA) which promote the growth and differentiation of stem cells into colonies of specific blood cells.

Approved Diagnosis:

- Anemia of chronic renal failure
- Anemia in post renal-transplant patients
- Anemia in cancer chemotherapy-treated patients
- Anemia due to myelosuppressive medication regimen for HIV
- Anemia due to myelosuppressive medication regimen Hepatitis C
- Decrease need for blood transfusions in surgery patients
- Anemia due to idiopathic sideroblastic anemia/myelodysplastic syndrome

Coverage Guidelines

Authorization may be reviewed on a case by case basis for members new to Mass General Brigham Health Plan who are currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted for members when ALL the following criteria are met, and documentation is provided:

Anemia due to Chronic Kidney Disease (CKD)

1. Appropriate diagnosis
2. **ONE** of the following:
 - a. Hemoglobin (Hb) < 10 g/dL (dated within the last 60 days)
 - b. Member is a child and is noted to be symptomatic with a Hb ≤ 11 g/dL
 - c. Member is noted to be stable on one of the ESA agents previously and Hb ≤ 12 g/dL (dated within the last 60 days)

- d. Member is noted to be stable on one of the ESA agents previously and Hb >12 g/dL (dated within the last 60 days), prescriber attestation that erythropoietin dose will be held or reduced to remain within appropriate target
3. **ONE** of the following:
 - a. Estimated or measured glomerular filtration rate (GFR) \leq 30 mL/min §
 - b. Estimated or measured glomerular filtration rate (GFR) 30-60 mL/min noting that other causes of anemia have been ruled out (iron, vitamin B12, folate deficiency and hemolysis) §
4. Member is NOT receiving hemodialysis ‡

§ For all GFR calculations, please use the [calculator](#) provided by the National Kidney Foundation:

‡ If member is receiving hemodialysis, prescriber must contact dialysis clinic for proper billing procedure as medication is provided by the clinic.

Anemia post-renal transplant

1. Appropriate diagnosis
2. **ONE** of the following:
 - a. Hb < 10 g/dL (dated within the last 60 days)
 - b. Member is a child and is noted to be symptomatic with a Hb \leq 11 g/dL
3. Member is NOT receiving hemodialysis ‡

‡ If member is receiving hemodialysis, prescriber must contact dialysis clinic for proper billing procedure as medication is provided by the clinic.

Anemia due to chemotherapy treatment for cancer

1. Appropriate diagnosis
2. **ONE** of the following:
 - a. Hb < 10 g/dL (dated within the last 60 days)
 - b. Member is a child and is noted to be symptomatic with a Hb \leq 11 g/dL

Anemia due to a myelosuppressive medication regimen for HIV

1. Appropriate diagnosis
2. **ONE** of the following:
 - a. Paid claim or physician documented medication regimen includes zidovudine or zidovudine-containing products
 - b. All other causes of anemia have been ruled out (iron, vitamin B12, folate deficiency, and hemolysis)
3. **ONE** of the following:
 - a. Hb < 10 g/dL (dated within the last 60 days)
 - b. Member is a child and is noted to be symptomatic with a Hb \leq 11 g/dL

Anemia due to myelosuppressive medication regimen for Hepatitis C

1. Appropriate diagnosis
2. **ONE** of the following:
 - a. Hb < 10 g/dL (dated within the last 60 days) * and member is currently being treated with a hepatitis C regimen containing an interferon product (with or without ribavirin)
 - b. Hb < 10 g/dL (dated within the last 60 days) * and member is currently being treated with a hepatitis C regimen containing ribavirin without interferon, and ribavirin dose reduction to 600 mg per day has been attempted
 - c. Member is currently being treated with a hepatitis C regimen containing ribavirin without interferon and ribavirin dose reduction to 600 mg per day is not indicated by ONE of the following:
 - i. Hb <8.5 g/dL (dated within the last 60 days)



- ii. Hb < 12 g/dL (dated within the last 60 days) and history of cardiac disease

*If member is a child and is noted to be symptomatic with a hemoglobin level less than or equal to 11 g/dL request can be approved if all other criterion is met

Decrease need for blood transfusions in surgery patients

1. Appropriate diagnosis (including members who refuse blood donation due to religious beliefs)
2. Hb ≤13 g/dL (dated within the last 30 days)
3. Surgery planned within the next 3 months (Anticipated date of surgery)

Anemia due to idiopathic sideroblastic anemia/myelodysplastic syndrome (MDS)

1. Appropriate diagnosis
2. **ONE** of the following:
 - a. Hb < 10 g/dL (dated within the last 60 days)
 - b. Member is a child and is noted to be symptomatic with a Hb ≤ 11 g/dL

Continuation of Therapy

Anemia due to:

Chronic Kidney Disease, Post-Renal Transplant

1. **ONE** of the following:
 - a. Hb level < 11.5 g/dL (dated within the last 60 days)
 - b. Hb level ≥ 11.5 g/dL (dated within the last 60 days) and the request addresses if the erythropoietin dose is to be held or reduced to remain with the appropriate target.

Idiopathic Sideroblastic Anemia, Myelodysplasia (MDS)

1. **ONE** of the following:
 - a. Hb level ≤ 12 g/dL (dated within the last 60 days)
 - b. Hb level > 12 g/dL (dated within the last 60 days) and the request addresses if the erythropoietin dose is to be held or reduced to remain with the appropriate target.

Chemotherapy Treatment for Cancer or Myelosuppressive medication regimen for HIV

1. Hb level ≤12 g/dL (dated within the last 60 days)
2. Paid claims or physician documentation that member continues to receive the causative agent

Myelosuppressive medication regimen for Hepatitis C (with or without ribavirin dose reduction)

1. Paid claims or physician documentation that the member continues to receive the causative agent

Limitations

1. Initial authorizations will be approved based on indication:
 - a. Anemia of chronic renal failure: **12 months**
 - b. Anemia post-renal transplant: **6 months**
 - c. Anemia due to chemotherapy for cancer: **3 months**
 - d. Anemia in HIV: **6 months**
 - e. Anemia in Hepatitis C: **3 months**
 - f. Anemia due to surgery: **2 months**
 - g. Anemia due to idiopathic sideroblastic anemia/MDS: **6 months**
2. Reauthorizations will be approved based on indication:
 - a. Anemia due to CRF: **12 months**



- b. Anemia due to chemotherapy treatment for cancer and myelosuppressive medication for HIV: **3 months**
- c. Anemia due to myelosuppressive medication regimen for Hepatitis C: **3 months**
- d. All other diagnosis: **6 months**

References

1. Epogen [package insert]. Thousand Oaks, CA: Amgen Inc.; April 2024.
2. Procrit [package insert]. Horsham, PA: Janssen Products.; May 2024.
3. Retacrit [package insert]. Lake Forest, IL: Hospira Inc.; June 2024.
4. Aranesp (darbepoetin alfa) [prescribing information]. Thousand Oaks, CA: Amgen Inc; May 2024.
5. National Comprehensive Cancer Network. The NCCN Drugs & Biologics Compendium. <http://www.nccn.org>. Accessed September 19, 2018.
6. Micromedex Solutions [database online]. Ann Arbor, MI: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. Accessed September 19, 2018.
7. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed September 19, 2018.
8. 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.
9. 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.
10. 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.
11. 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, 2017.
12. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Myelodysplastic Syndromes. Version 1.2019. http://www.nccn.org/professionals/physician_gls/pdf/mds.pdf. Accessed September 19, 2017.
13. 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.
14. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Myeloproliferative Neoplasms. Version 1.2019. https://www.nccn.org/professionals/physician_gls/pdf/mpn.pdf. Accessed September 19, 2017.
15. 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.
16. Henry DH, Beall GN, Benson CA, Carey J, Cone LA, Eron LJ, et al. Recombinant Human Erythropoietin in the Treatment of Anemia Associated with Human Immunodeficiency Virus (HIV) Infection and Zidovudine Therapy: Overview of Four Clinical Trials. *Ann Intern Med.*; 117:739–748. doi: 10.7326/0003-4819-117-9-739.
17. Gabrilove j, Paquette R, Lyons R, Mushtaq C, Sekeres M, Tomita D, Dreiling L. Phase 2, single-arm trial to evaluate the effectiveness of darbepoetin alfa for correcting anaemia in patients with myelodysplastic syndromes. *Br J Haematol.* 2008 Aug; 142(3): 379–393.



Review History

10/15/2020 – Reviewed Nov P&T Mtg; Transitioned from SGM to custom criteria; updated references; Effective 1/1/21 Updated to be in compliance with the Masshealth partial unified formulary requirements

03/17/2021 – Reviewed and Updated; approvable indications were updated with notes. Allowed higher Hgb threshold for children with symptomatic anemia per MH UPPL

06/22/2022 - Reviewed and updated for June P&T; matched MH UPPL. Guideline updated to make Epogen® the preferred epoetin alfa product and therefore Procrit® and Retacrit® now require prior use criteria for Epogen®. Continuation of therapy section was updated. Updated References. Effective 08/01/2022.

04/12/23 – Reviewed and updated for Apr P&T. Moved appendix criteria (off label indication) to Coverage Guidelines. Guideline update to clarify NCQA update for anemia due to myelosuppressive medication regimen for Hepatitis C and ribavirin dose reduction not indicated.

05/10/23 – Reviewed and updated for P&T. Separated Rx vs MB policies. Removed preferred product requirement for requests under MB. Effective 6/5/23.

09/13/23 – Reviewed and updated for P&T. Clarified criteria for members who have anemia due to CRF who were stable on one of the ESAs previously (not a new member and no previous approval on file) with higher Hb levels must meet initial criteria. Formatting updates. Effective 10/2/23.

05/15/2025 – Reviewed and updated for P&T. Performed annual medical criteria review. Policy has been updated to better reflect agents with prior authorization on medical benefit. Mircera was available on medical benefit without prior authorization and thus has been removed. Updated formatting and references accordingly. Effective 6/1/2025

11/12/25 - Reviewed and updated for P&T. Updated Hb thresholds in continuation criteria. Documented GFR can now be estimated or measured. Remove Retacrit as drug will not require PA on both benefits. Effective 1/1/26

