

# Erythropoiesis Stimulating Agents Aranesp (darbepoetin alfa) Epogen (epoetin alfa) Procrit (epoetin alfa) Retacrit (epoetin alfa-epbx) Effective 06/01/2025

Plan	☑ MassHealth UPPL □Commercial/Exchange		<ul> <li>☑ Prior Authorization</li> <li>□ Quantity Limit</li> <li>□ Step Therapy</li> </ul>
Benefit	<ul> <li>Pharmacy Benefit</li> <li>Medical Benefit</li> </ul>	Program Type	
Specialty Limitations	N/A		
	Medical and Specialty Medications		
Contact	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
Information	Non-Specialty Medications		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
Notes	Aranesp, Epogen, Procrit, and Retacrit 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 Renal Failure (CRF)

- 1. Appropriate diagnosis
- 2. **ONE** of the following:

Mass General Brigham Health Plan includes Mass General Brigham Health Plan, Inc. and Mass General Brigham Health Insurance Company.

- 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  $\leq$  11 g/dL
- c. Member is noted to be stable on one of the ESA agents previously and Hb  $\leq$  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. Glomerular filtration rate (GFR)  $\leq$  30 mL/min §
  - b. 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 <u>calculator</u> 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 zidovudinecontaining 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  $\leq$ 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  $\leq$  11 g/dL

### **Continuation of Therapy**

Anemia due to:

Chronic Renal Failure, Post-Renal Transplant, Idiopathic Sideroblastic Anemia, Myelodysplasia (MDS)

- 1. **ONE** of the following:
  - a. Hb level  $\leq 12$  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  $\leq 12 \text{ g/dL}$  (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 regiment 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.
- Micromedex Solutions [database online]. Ann Arbor, MI: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. Accessed September 19, 2018.
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### **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<sup>®</sup> the preferred epoetin alfa product and therefore Procrit<sup>®</sup> and Retacrit<sup>®</sup> now require prior use criteria for Epogen<sup>®</sup>. 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

