Mass General Brigham
Health Plan

Erythropoiesis Stimulating Agents
Aranesp (darbepoetin alfa)
Epogen (epoetin alfa)
Procrit (epoetin alfa)
Effective 01/04/2027

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
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
If member is new to the plan (as evidenced by coverage effective date of less than or equal to 90 days), submission of medical records documenting that the member is currently receiving treatment with the requested drug, excluding when the product is obtained as samples or via manufacturer's patient assistance programs
OR
Authorization may be granted when all of the following criteria are met:

Anemia due to Chronic Kidney Disease (CKD)
1. Diagnosis of anemia due to chronic kidney disease
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 ≤ 11.5 g/dL (dated within the last 60 days)

    d. Member is noted to be stable on one of the ESA agents previously and Hb >11.5 g/dL (dated within the last 60 days), prescriber attestation that erythropoietin dose will be held or reduced to remain within appropriate target
3. Estimated or measured glomerular filtration rate (GFR) ≤ 60 mL/min §
4. Member is NOT receiving hemodialysis ‡
5. Requested strength is the minimum strength necessary to administer the requested dose

§ 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. Diagnosis of anemia due to renal transplant
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
3. Member is NOT receiving hemodialysis ‡
4. Requested strength is the minimum strength necessary to administer the requested dose

‡ 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. Diagnosis of anemia due to chemotherapy treatment for cancer
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
3. Requested strength is the minimum strength necessary to administer the requested dose

Anemia due to a myelosuppressive medication regimen for HIV

1. Diagnosis of anemia due to a myelosuppressive medication regimen for HIV
2. **ONE** of the following:
    a. Requested agent will be used in combination with 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 ≤ 11 g/dL
4. Requested strength is the minimum strength necessary to administer the requested dose

Anemia due to myelosuppressive medication regimen for Hepatitis C

1. Diagnosis of anemia due to a myelosuppressive medication regimen for Hepatitis C
2. **ONE** of the following:
    a. Member is a child and is noted to be symptomatic with a Hb ≤ 11 g/dL
    b. 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)
    c. 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
    d. 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

3. Requested strength is the minimum strength necessary to administer the requested dose

Decrease need for blood transfusions in surgery patients

1. Indication to decrease the need for blood transfusion with surgery (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)
4. Requested strength is the minimum strength necessary to administer the requested dose

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

1. Diagnosis of ONE of the following:
    a. Idiopathic sideroblastic anemia
    b. Anemia due to myelodysplastic syndrome (MDS)
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
3. Requested strength is the minimum strength necessary to administer the requested dose

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. Requested agent will be used in combination with causative agent

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

1. Documentation that the member will continue 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.
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3. Retacrit [package insert]. Lake Forest, IL: Hospira Inc.; June 2024.
4. Aranesp (darbepoetin alfa) [prescribing information]. Thousand Oaks, CA: Amgen Inc; May 2024.
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Zidovudine Therapy: Overview of Four Clinical Trials. Ann Intern Med.; 117:739–748. doi: 10.7326/0003-4819-117-9-739.
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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® 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
11/4/26 – Reviewed and updated for P&T. Updated Hb thresholds from 11 to 11.5 g/dL. Added the criteria point of requested strength being the minimum strength necessary to administer the requested dose for all indications. Updated formatting. Effective 1/4/27