Mass General Brigham
Health Plan

Epogen, Procrit (epoetin alfa)
Retacrit (epoetin alfa-epbx)
Aranesp (darbepoetin alfa)
Effective 10/02/2023

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 and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	N/A		

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

No PA	PA required
Mircera® (methoxy polyethylene glycol/epoetin beta)[MB]	Aranesp® (darbepoetin alfa)
	Epogen® (epoetin alfa)
	Procrit® (epoetin alfa)
	Retacrit® (epoetin alfa-epbx)

MB – Medical Benefit

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)
ALL of the following:
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. Glomerular filtration rate (GFR) ≤ 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 calculator provided by the National Kidney Foundation: (https://www.kidney.org/professionals/KDOQI/gfr_calculator)
‡ 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
ALL of the following:
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
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
ALL of the following:
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

Anemia due to a myelosuppressive medication regimen for HIV
ALL of the following:
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 ≤ 11 g/dL

Anemia due to myelosuppressive medication regimen for Hepatitis C

ALL of the following:

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

ALL of the following:

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)

ALL of the following:

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

Prescriber provides documentation of **ALL** of the following:

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

Prescriber provides documentation of **ALL** of the following:

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)
Prescriber provides documentation of **ALL** of the following:

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.; July 2018.
2. Procrit [package insert]. Horsham, PA: Janssen Products.; July 2018.
3. Retacrit [package insert]. Lake Forest, IL: Hospira Inc.; September 2020.
4. Aranesp (darbepoetin alfa) [prescribing information]. Thousand Oaks, CA: Amgen Inc; February 2019.
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.
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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