Mass General Brigham
Health Plan

Epogen, Procrit (epoetin alfa)
Retacrit (epoetin alfa-epbx)
Aranesp (darbepoetin alfa)
Effective 08/01/2022

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit (NLX)		
Specialty Limitations	These medications have been designated specialty and must be filled at a contracted specialty pharmacy when obtained through the pharmacy benefit.		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions			

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)	Aranesp® (darbepoetin alfa)
	Epogen® (epoetin alfa)
	Procrit® (epoetin alfa)
	Retacrit® (epoetin alfa-epbx)

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 the 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)
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. Hemoglobin (Hb) < 10 g/dL (dated within the last 60 days) †
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‡
5. If the request is for Procrit® or Retacrit®, clinical rationale for use of the requested agent instead of Epogen®

Anemia post-renal transplant
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. Hb < 10 g/dL (dated within the last 60 days) †
3. Member is NOT receiving hemodialysis†
4. If the request is for Procrit® or Retacrit®, clinical rationale for use of the requested agent instead of Epogen®

Anemia due to chemotherapy treatment for cancer
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. Hb < 10 g/dL (dated within the last 60 days) †
3. If the request is for Procrit® or Retacrit®, clinical rationale for use of the requested agent instead of Epogen®

Anemia due to a myelosuppressive medication regimen for HIV
Prescriber provides documentation of **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. Hb < 10 g/dL (dated within the last 60 days) †
4. If the request is for Procrit® or Retacrit®, clinical rationale for use of the requested agent instead of Epogen®

Anemia due to myelosuppressive medication regimen for Hepatitis C
Prescriber provides documentation of **ALL** of the following:

1. Appropriate diagnosis
2. Hb < 10 g/dL (dated within the last 60 days) †
3. **ONE** of the following:
    a. Paid claim or physician documentation that member is currently being treated with a hepatitis C regimen containing an interferon product (with or without ribavirin)
    b. **ALL** of the following†
        i. Paid claim or physician documentation that member is currently being treated with a hepatitis C regimen containing ribavirin
        ii. Member's hepatitis C regimen does **NOT** contain interferon
        iii. Prescriber documents ribavirin dose reduction to 600 mg per day has been attempted§
4. If the request is for Procrit® or Retacrit®, clinical rationale for use of the requested agent instead of Epogen®

<u>Decrease need for blood transfusions in surgery patients</u>
Prescriber provides documentation of **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)
4. If the request is for Procrit® or Retacrit®, clinical rationale for use of the requested agent instead of Epogen®

<u>Anemia due to idiopathic sideroblastic anemia/myelodysplastic syndrome (MDS)</u>
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. Hb < 10 g/dL (dated within the last 60 days) †
3. If the request is for Procrit® or Retacrit®, clinical rationale for use of the requested agent instead of Epogen®

§ 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.
†If member is a child and is noted to be symptomatic with a Hb level ≤11 g/dL, request can be approved if all other criterion is met.

<u>Continuation of Therapy</u>
Anemia due to:
<u>Chronic Renal Failure, Post-Renal Transplant, Idiopathic Sideroblastic Anemia, Myelodysplasia (MDS)</u>
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.
2. If the request is for Procrit® or Retacrit®, clinical rationale for use of the requested agent instead of Epogen®

<u>Chemotherapy Treatment for Cancer or Myelosuppressive medication regimen for HIV</u>
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
3. If the request is for Procrit® or Retacrit®, clinical rationale for use of the requested agent instead of Epogen®

Myelosuppressive medication regimen for Hepatitis C

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

1. Paid claims or physician documentation that the member continues to receive the causative agent
2. If the request is for Procrit® or Retacrit®, clinical rationale for use of the requested agent instead of Epogen®

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

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3. Retacrit [package insert]. Lake Forest, IL: Hospira Inc.; September 2020.
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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.