



**Epogen, Procrit (epoetin alfa)
Retacrit (epoetin alfa-epbx)
Aranesp (darbepoetin alfa)
Mircera (methoxy polyethylene glycol-epoetin beta)
Effective 08/01/2022**

Plan	<input type="checkbox"/> MassHealth <input checked="" type="checkbox"/> MassHealth (PUF) <input type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input checked="" type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit (NLX)		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
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	Mircera is available on MB only		

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 AllWays Health Partners 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) \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 ‡
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[®]

Decrease need for blood transfusions in surgery patients

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[®]

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

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.

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.
2. If the request is for Procrit[®] or Retacrit[®], clinical rationale for use of the requested agent instead of Epogen[®]

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
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 regimen 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.
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9. National Kidney Foundation. KDOQI Clinical Practice Guideline and Clinical Practice Recommendations for Anemia in Chronic Kidney Disease: 2007 Update of Hemoglobin Target.

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 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.
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 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.
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 18. Mircera (methoxy polyethylene glycol-epoetin beta) [prescribing information]. South San Francisco, CA: Hoffmann-La Roche Inc; June 2018.

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.

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