



Erythropoiesis Stimulating Agents (Procrit®, Epogen®, Retacrit™, Aranesp®) EOCCO POLICY



Policy Type: PA/SP

Pharmacy Coverage Policy: EOCCO124

Description

Epoetin alfa (Retacrit, Procrit, Epogen) is a glycoprotein that stimulates red blood cell production; whereas, darbepoetin alfa (Aranesp) stimulates erythropoiesis by the same mechanism as endogenous erythropoietin.

Length of Authorization

Initial and Renewal:

Epoetin alfa (Procrit, Epogen, Retacrit):

- Chronic kidney disease with or without dialysis – Three months
- Cancer chemotherapy – 12 months
- Anemia due to zidovudine therapy – 12 months
- Allogeneic blood transfusion in surgery patients – 14-days

Darbepoetin alfa (Aranesp):

- Chronic kidney disease with or without dialysis – Three months
- Cancer chemotherapy – 12 months

Quantity Limits

Product Name	Dosage Form	Indication	Quantity Limit
darbepoetin alfa (Aranesp)	25 mcg/mL vial	Chronic Kidney Disease With or Without Dialysis; Cancer chemotherapy	4 vials/syringes per 30 days
	40 mcg/mL vial		
	60 mcg/mL vial		
	100 mcg/mL vial		
	150 mcg/mL vial		
	200 mcg/0.75 mL vial		
	300 mcg/mL vial		
	10 mcg/0.4 mL syringe		
	25 mcg/0.42 mL syringe		
	40 mcg/0.4 mL syringe		
	60 mcg/0.3 mL syringe		



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	100 mcg/0.5 syringe		
	150 mcg/0.3 syringe		
	200 mcg/0.4 mL syringe		
	300 mcg/0.6 mL syringe		
	500 mcg/mL syringe		
epoetin alfa (Retacrit)	2000 units/mL vial	Chronic Kidney Disease With or Without Dialysis; Cancer chemotherapy; Anemia due to zidovudine therapy; Allogeneic blood transfusion	2,000U, 3,000U, 4,000U and 10,000U vials: 12 vials per 30 days 20,000U and 40,000U vials: 4 vials per 30 days
	3000 units/mL vial		
	4000 units/mL vial		
	10000 units/mL vial		
	40000 units/mL vial		
epoetin alfa (Procrit)	2000 units/mL vial	Chronic Kidney Disease With or Without Dialysis; Cancer chemotherapy; Anemia due to zidovudine therapy; Allogeneic blood transfusion	2,000U, 3,000U, 4,000U and 10,000U vials: 12 vials per 30 days 20,000U and 40,000U vials: 4 vials per 30 days
	3000 units/mL vial		
	4000 units/mL vial		
	10000 units/mL vial		
	20000 units/mL vial		
	20000 units/2 mL vial		
	40000 units/mL vial		
epoetin alfa (Epogen)	2000 units/mL vial	Chronic Kidney Disease With or Without Dialysis; Cancer chemotherapy; Anemia due to zidovudine therapy; Allogeneic blood transfusion	2,000U, 3,000U, 4,000U and 10,000U vials: 12 vials per 30 days 20,000U and 40,000U vials: 4 vials per 30 days
	3000 units/mL vial		
	4000 units/mL vial		
	10000 units/mL vial		
	20000 units/mL vial		
	20000 units/2 mL vial		

Initial Evaluation

- I. **Darbepoetin alfa (Aranesp), epoetin alfa (Procrit, Epogen, Retacrit)** may be considered medically necessary when the following criteria below are met:
 - A. Lab values are obtained within 30 days of administration (unless otherwise indicated); **AND**
 - B. Prior to initiation of therapy, member should have adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) $\geq 20\%$; **AND**
 - C. Initiation of therapy Hemoglobin (Hb) < 10 g/dL and/or Hematocrit (Hct) $< 30\%$ (unless otherwise specified); **AND**
 - D. A diagnosis of one of the following when the request is for **darbepoetin alfa (Aranesp) or epoetin alfa (Procrit, Epogen, Retacrit)**:
 1. **Anemia secondary to myelodysplastic syndrome (MDS); AND**



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- i. Member has an endogenous serum erythropoietin level of ≤ 500 mUnits/mL; **AND**
 - ii. Member has lower risk disease [i.e. defined as IPSS-R (Very Low, Low, Intermediate), IPSS (Low/Intermediate-1), WPSS (Very Low, Low, Intermediate)]; **AND**
 - a. Used for treatment of symptomatic anemia, as an alternative to lenalidomide, in patients with del(5q); **OR**
 - b. Used for treatment of symptomatic anemia in patients without del(5q); **AND**
 - i. Patient has ring sideroblasts $< 15\%$ and used as a single agent **OR** in combination with lenalidomide in patients who have failed single agent therapy; **OR**
 - ii. Patient has ring sideroblasts $\geq 15\%$ and used in combination with a granulocyte-colony stimulating factor (G-CSF); **OR**
2. **Anemia secondary to Myeloproliferative Neoplasms (MPN) – Myelofibrosis; AND**
- i. Member has an endogenous serum erythropoietin level of < 500 mUnits/mL; **OR**
3. **Anemia secondary to chemotherapy treatment; AND**
- i. Member is receiving concomitant myelosuppressive chemotherapy; **AND**
 - ii. Chemotherapy treatment plan is not intended to cure the disease (i.e. palliative chemotherapy); **AND**
 - iii. There are a minimum of two additional months of planned chemotherapy; **OR**
4. **Anemia secondary to chronic kidney disease; AND**
- i. Member is at least one month of age or older; **OR**
- E. A diagnosis of one of the following when the request is for **epoetin alfa (Procrit, Epogen, Retacrit)**:
1. **Anemia secondary to rheumatoid arthritis; OR**
 2. **Anemia secondary to zidovudine treated, HIV-infected members; AND**
 - i. Member has an endogenous serum erythropoietin level of < 500 mUnits/mL; **AND**
 - ii. Member is receiving zidovudine administered at ≤ 4200 mg/week; **OR**
 3. **Reduction of allogenic blood transfusions in elective, non-cardiac, non-vascular surgery; AND**
 - i. Hemoglobin (Hb) between 10 g/dL and 13 g/dL and/or Hematocrit (Hct) between 30% and 39%; **AND**
 - ii. Patient is at high-risk of blood-loss from surgery that is elective, non-cardiac and non-vascular; **AND**



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- iii. Patient is unwilling or unable to participate in an autologous blood donation program prior to surgery
- II. Darbepoetin alfa (Aranesp), epoetin alfa (Procrit, EPOgen, Retacrit) are considered investigational when used for all other conditions.

Renewal Evaluation

- I. Lab values are obtained within 30 days of the date of administration (unless otherwise indicated); **AND**
- II. Adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) $\geq 20\%$ measured within the previous 3 months; **AND**
- III. Documentation of disease response indicated by Hemoglobin (Hb) and/or Hematocrit (Hct) as follows:

Indication	Hb and/or Hct Response
Anemia secondary to myelodysplastic syndrome (MDS)	Hemoglobin (Hb) <12 g/dL and/or Hematocrit (Hct) <36%
Anemia secondary to myeloproliferative neoplasms (MF, post-PV myelofibrosis, post-ET myelofibrosis)	Hemoglobin (Hb) <10 g/dL and/or Hematocrit (Hct) <30%
Reduction of allogeneic blood transfusions in elective, non-cardiac, non-vascular surgery	Hemoglobin(Hb) between 10 g/dL and 13 g/dL and/or Hematocrit(Hct) between 30% and 39%
Anemia secondary to chemotherapy treatment	Hemoglobin (Hb) <10 g/dL and/or Hematocrit (Hct) < 30%
Anemia secondary to zidovudine treated, HIV-infected patients	Hemoglobin (Hb)< 12 g/dL and/or Hematocrit (Hct) < 36%;
Anemia secondary to chronic kidney disease	<i>Pediatric patients:</i> Hemoglobin (Hb) < 12 g/dL and/or Hematocrit (Hct) < 36% <i>Adults:</i> Hemoglobin (Hb) < 11 g/dL and/or Hematocrit (Hct) < 33%
All other indications	Hemoglobin (Hb) < 11 g/dL and/or Hematocrit (Hct) < 33%



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Policy Implementation/Update:

Date Created	June 2011
Date Effective	June 2011
Last Updated	November 2012
Last Reviewed	08/2012, 11/2012, 10/2018, 11/2019

Action and Summary of Changes	Date
Removed box stating Retacrit is preferred product. Removed requirement to try/fail Retacrit before others.	01/2019
<ul style="list-style-type: none"> • Transitioned to policy format • Added language regarding preferred product, Retacrit and removal of PA requirement • Aligned criteria with medical benefit for consistency across benefits, which included clarifying initial requirements (e.g. labs obtained within 30 days, adequate iron stores, Hg/Hct levels) • Added coverage criteria for anemia associated with rheumatoid arthritis, anemia secondary to MDS, and anemia secondary to myelofibrosis 	12/2019



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<ul style="list-style-type: none">• Added specific renewal criteria	
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