

Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date:	August 18, 2021
Revision Date:	February 21, 2022; January 24, 2024

Erythropoiesis Stimulating Agents

Preferred drugs (Clinical PA): Aranesp[®] (darbepoetin alfa), Epogen[®] (epoetin alfa), (Pfizer) Retacrit[®] (epoetin alfa-epbx)

Non-preferred drugs: Mircera[®] (methoxy polyethylene glycol-epoetin beta), Procrit[®] (epoetin alfa), (Vifor) Retacrit[®] (epoetin alfa-epbx)

LENGTH OF AUTHORIZATION: Initiation of therapy: Up to 3 months Continuation of therapy: Up to 6 months

INITIAL REVIEW CRITERIA:

- Medication requested must have the FDA approved indication and patient must be within the FDA approved age limits.
- Trial and failure to therapy of a preferred medication (e.g., Aranesp[®], Epogen[®], or Pfizer Retacrit[®]) is required before approval of a non-preferred medication.

Drug	Indications	Criteria
Aranesp®	Anemia associated with chronic kidney disease if patient is not on dialysis	Adult Patients Initial Review Therapy ○ Patient must have hemoglobin < 10g/dL, transferrin saturation ≥ 20% and serum ferritin ≥ 100ng/mL. ○ Patient must have lab data submitted within 2 months of PA submission. Continuation of Therapy ○ Patient must have hemoglobin ≤ 10 g/dL, transferrin saturation ≥ 20% and serum ferritin ≥ 100ng/mL. ○ Patient must have lab data submitted within 2 months of PA submission. Pediatric Patients Initial Review Criteria ○ Patient must have hemoglobin < 10 g/dL, transferrin saturation ≥ 20% and serum ferritin ≥ 100ng/mL. ○ Patient must have lab data submitted within 2 months of PA submission. Continuation of Therapy ○ Patient must have hemoglobin ≤ 12 g/dL, transferrin saturation ≥ 20% and serum ferritin ≥ 100ng/mL. ○ Patient must have lab data submitted within 2 months of PA submission.



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	Anemia associated with	Adult Patients Litial Parior Thomas
	chronic kidney disease if patient is on dialysis	Initial Review Therapy Potient must have homoglable < 100/dL transformin activation > 200/
	patient is on dialysis	o Patient must have hemoglobin < 10g/dL, transferrin saturation ≥ 20%
		and serum ferritin ≥ 100ng/mL. ○ Patient must have lab data submitted within 2 months of PA
		submission.
		Continuation of Therapy
		o Patient must have hemoglobin ≤ 11 g/dL, transferrin saturation $\geq 20\%$
		and serum ferritin ≥ 100ng/mL.
		o Patient must have lab data submitted within 2 months of PA
		submission.
		Pediatric Patients
		Initial Review Criteria
		o Patient must have hemoglobin < 10 g/dL, transferrin saturation ≥
		20% and serum ferritin ≥ 100ng/mL.
		o Patient must have lab data submitted within 2 months of PA
		submission.
		Continuation of Therapy
		o Patient must have hemoglobin \leq 12 g/dL, transferrin saturation \geq 20%
		and serum ferritin ≥ 100 ng/mL.
		o Patient must have lab data submitted within 2 months of PA
		submission.
	Anemia associated with	Initial Therapy
	chemotherapy	o Patient has no existing history of iron or folate deficiency, hemolysis,
		or gastrointestinal bleeding.
		o Patient must have hemoglobin < 10 g/dL, transferrin saturation ≥ 20%
		and serum ferritin $\geq 100 \text{ng/mL}$.
		Must be on or initiating chemotherapy (minimum of 2 months).
		industrial of an of minimum of 2 monator,
		Continuation of Therapy
		o Patient has no existing history of iron or folate deficiency, hemolysis,
		or gastrointestinal bleeding.
		o Patient must have hemoglobin < 10 g/dL or lowest level sufficient to
		avoid transfusion.
		o Patient must have transferrin saturation ≥ 20% and serum ferritin ≥
		100ng/mL.
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D	Anemia associated with	Adult Patients
Retacrit®	chronic kidney disease if	Initial Review Therapy
	patient is not on dialysis	\circ Patient must have hemoglobin < $10g/dL$, transferrin saturation $\ge 20\%$
	patient is not on diarysis	and serum ferritin $\geq 100 \text{ng/mL}$.
		Patient must have lab data submitted within 2 months of PA
		submission.
		Continuation of Therapy
		o Patient must have hemoglobin ≤ 10 g/dL, transferrin saturation $\geq 20\%$
		and serum ferritin ≥ 100 ng/mL.
		Patient must have lab data submitted within 2 months of PA
		submission.
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		<u>Pediatric Patients</u>
		Initial Review Criteria
		 ○ Patient must have hemoglobin < 10 g/dL, transferrin saturation ≥
		20% and serum ferritin ≥ 100ng/mL.
		o Patient must have lab data submitted within 2 months of PA
		submission.
		Continuation of Therapy
		o Patient must have hemoglobin ≤ 12 g/dL, transferrin saturation $\geq 20\%$
		and serum ferritin ≥ 100 ng/mL.
		Patient must have lab data submitted within 2 months of PA
		submission.
-	Anemia associated with	Adult Patients
	chronic kidney disease if	Initial Review Therapy
	patient is on dialysis	o Patient must have hemoglobin < 10g/dL, transferrin saturation ≥ 20%
		and serum ferritin ≥ 100ng/mL.
		Patient must have lab data submitted within 2 months of PA
		submission.
		Continuation of Therapy
		o Patient must have hemoglobin ≤ 11 g/dL, transferrin saturation $\geq 20\%$
		and serum ferritin ≥ 100ng/mL.
		 Patient must have lab data submitted within 2 months of PA
		submission.
		<u>Pediatric Patients</u>
		Initial Review Criteria
		 ○ Patient must have hemoglobin < 10 g/dL, transferrin saturation ≥
		20% and serum ferritin ≥ 100 ng/mL.
		o Patient must have lab data submitted within 2 months of PA
		submission.
		Continuation of Therapy
		o Patient must have hemoglobin ≤ 12 g/dL, transferrin saturation $\geq 20\%$
		and serum ferritin ≥ 100ng/mL.
		o Patient must have lab data submitted within 2 months of PA
		submission.
	Anemia associated with	Initial Therapy
	chemotherapy	Patient has no existing history of iron or folate deficiency, hemolysis,
	chemotherapy	or gastrointestinal bleeding.
		o Patient must have hemoglobin $< 10 \text{ g/dL}$, transferrin saturation $\ge 20\%$
		and serum ferritin ≥ 100 ng/mL.
		Continuation of Therapy
		Patient has no existing history of iron or folate deficiency, hemolysis,
		or gastrointestinal bleeding.
		o Patient must have hemoglobin < 10 g/dL or lowest level sufficient to
		avoid transfusion.
		o Patient must have transferrin saturation ≥ 20% and serum ferritin ≥
		100ng/mL.
	Anemia associated with	Initial Therapy
	Zidovudine in HIV therapy	o Patient has no existing history of iron or folate deficiency, hemolysis,
		or gastrointestinal bleeding.



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	To reduce the need for allogenic blood transfusions in anemic patients scheduled to undergo elective, noncardiac, nonvascular surgery	 ○ Patient must be receiving Zidovudine ≤ 4200 mg/week with serum erythropoietin levels ≤ 500 mUnits/mL. ○ Patient must have transferrin saturation ≥ 20% and serum ferritin ≥ 100ng/mL. Continuation of Therapy ○ Patient must be receiving Zidovudine given at ≤ 4200 mg/week and have serum erythropoietin levels ≤ 500 mUnits/mL. ○ Patient must have transferrin saturation ≥ 20% and serum ferritin ≥ 100ng/mL. ○ Withhold if hemoglobin >12 g/dL, resume at a lower dose when hemoglobin <11 g/dL. ○ Patient must be unwilling to donate blood. ○ Patient must have hemoglobin > 10 and ≤ 13 g/dL. ○ Patient must be receiving iron supplementation. ○ Approve no more than 15 doses.
Epogen [®]	Anemia associated with chronic kidney disease if patient is not on dialysis Anemia associated with chronic kidney disease if patient is on dialysis	Adult Patients Initial Review Therapy ○ Patient must have hemoglobin < 10g/dL, transferrin saturation ≥ 20% and serum ferritin ≥ 100ng/mL. ○ Patient must have lab data submitted within 2 months of PA submission. Continuation of Therapy ○ Patient must have hemoglobin ≤ 10 g/dL, transferrin saturation ≥ 20% and serum ferritin ≥ 100ng/mL. ○ Patient must have lab data submitted within 2 months of PA submission. Pediatric Patients Initial Review Criteria ○ Patient must have hemoglobin < 10 g/dL, transferrin saturation ≥ 20% and serum ferritin ≥ 100ng/mL. ○ Patient must have lab data submitted within 2 months of PA submission. Continuation of Therapy ○ Patient must have hemoglobin ≤ 12 g/dL, transferrin saturation ≥ 20% and serum ferritin ≥ 100ng/mL. ○ Patient must have lab data submitted within 2 months of PA submission. Adult Patients Initial Review Therapy ○ Patient must have hemoglobin < 10g/dL, transferrin saturation ≥ 20% and serum ferritin ≥ 100ng/mL. ○ Patient must have lab data submitted within 2 months of PA submission.



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	o Patient must have hemoglobin ≤ 11 g/dL, transferrin saturation ≥ 20%
	and serum ferritin ≥ 100ng/mL.
	 Patient must have lab data submitted within 2 months of PA
	submission.
	Pediatric Patients
	Initial Review Criteria
	o Patient must have hemoglobin < 10 g/dL, transferrin saturation ≥
	20% and serum ferritin ≥ 100ng/mL.
	Patient must have lab data submitted within 2 months of PA
	submission.
	Continuation of Therapy
	\circ Patient must have hemoglobin ≤ 12 g/dL, transferrin saturation $\geq 20\%$
	and serum ferritin ≥ 100 ng/mL.
	Patient must have lab data submitted within 2 months of PA
	submission.
Anemia associated with	Initial Therapy
chemotherapy	Patient has no existing history of iron or folate deficiency, hemolysis,
chemotherapy	or gastrointestinal bleeding.
	or gastromes that breeding. o Patient must have hemoglobin $< 10 \text{ g/dL}$, transferrin saturation $\ge 20\%$
	and serum ferritin ≥ 100 ng/mL.
	Must be on or initiating chemotherapy (minimum of 2 months).
	Continuation of Therapy
	o Patient has no existing history of iron or folate deficiency, hemolysis,
	or gastrointestinal bleeding.
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	O Patient must have hemoglobin < 10 g/dL or lowest level sufficient to avoid transfusion.
	 ○ Patient must have transferrin saturation ≥ 20% and serum ferritin ≥
	100ng/mL.
Anemia associated with	Initial Therapy
Zidovudine in HIV therapy	Patient has no existing history of iron or folate deficiency, hemolysis,
Zidovudine in m v therapy	or gastrointestinal bleeding.
	serum erythropoietin levels \le 500 mUnits/mL.
	o Patient must have transferrin saturation ≥ 20% and serum ferritin ≥
	100ng/mL.
	Continuation of Therapy
	o Patient must be receiving Zidovudine given at ≤ 4200 mg/week and
	have serum erythropoietin levels \le 500 mUnits/mL.
	o Patient must have transferrin saturation ≥ 20% and serum ferritin ≥
	100ng/mL.
	• Withhold if hemoglobin >12 g/dL, resume at a lower dose when
m 1 1 1 1 2	hemoglobin <11 g/dL.
To reduce the need for	Patient must be unwilling to donate blood.
allogenic blood	 Patient must have hemoglobin > 10 and ≤ 13 g/dL.
transfusions in anemic	Patient must be receiving iron supplementation.
patients scheduled to	o Approve no more than 15 doses.
undergo elective, non-	
cardiac, nonvascular	
surgery	



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Minor	Anemia associated with	Adult Patients
Mircera [®]	chronic kidney disease if	Initial Review Therapy
	patient is not on dialysis	o Patient must have hemoglobin < 10g/dL, transferrin saturation ≥ 20% and serum ferritin ≥ 100ng/mL.
		o Patient must have lab data submitted within 2 months of PA
		submission.
		Continuation of Therapy Potient must have homeelahin < 10 a/dL transferring actuation > 200
	 Patient must have hemoglobin ≤ 10 g/dL, transferrin saturation ≥ 20% and serum ferritin ≥ 100ng/mL. 	
		 Patient must have lab data submitted within 2 months of PA submission.
		Pediatric Patients
		Initial Review Criteria
		 Patient must have hemoglobin < 10 g/dL, transferrin saturation ≥ 20% and serum ferritin ≥ 100ng/mL.
		o Patient must have lab data submitted within 2 months of PA
		submission.
		Continuation of Therapy
		o Patient must have hemoglobin ≤ 12 g/dL, transferrin saturation ≥ 20 %
		and serum ferritin $\geq 100 \text{ng/mL}$.
		o Patient must have lab data submitted within 2 months of PA
		submission.
	Anemia associated with	Adult Patients Initial Review Therapy
	chronic kidney disease if patient is on dialysis	o Patient must have hemoglobin < 10g/dL, transferrin saturation $\geq 20\%$
	patient is on diarysis	and serum ferritin $\geq 100 \text{ng/mL}$, transferring saturation $\geq 20\%$
		o Patient must have lab data submitted within 2 months of PA
		submission.
		Continuation of Therapy
		 Patient must have hemoglobin ≤ 11 g/dL, transferrin saturation ≥ 20% and serum ferritin ≥ 100ng/mL.
		 Patient must have lab data submitted within 2 months of PA submission.
		Pediatric Patients Initial Review Criteria
		○ Patient must have hemoglobin < 10 g/dL, transferrin saturation ≥
		20% and serum ferritin ≥ 100ng/mL.
		o Patient must have lab data submitted within 2 months of PA
		submission.
		Continuation of Therapy
		 Patient must have hemoglobin ≤ 12 g/dL, transferrin saturation ≥ 20% and serum ferritin ≥ 100ng/mL.
		and serum ferritin ≥ 100ng/mL. o Patient must have lab data submitted within 2 months of PA
		submission.
	Pediatric patients on	Initial Review Criteria
	dialysis	o Patient must be 5 to 17 years of age.



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		Patient must be converting from another erythropoiesis-stimulating agent once hemoglobin is stable.
Procrit [®]	Anemia associated with chronic kidney disease if patient is not on dialysis	Adult Patients Initial Review Therapy ○ Patient must have hemoglobin < 10g/dL, transferrin saturation ≥ 20% and serum ferritin ≥ 100ng/mL. ○ Patient must have lab data submitted within 2 months of PA submission. Continuation of Therapy ○ Patient must have hemoglobin ≤ 10 g/dL, transferrin saturation ≥ 20% and serum ferritin ≥ 100ng/mL. ○ Patient must have lab data submitted within 2 months of PA submission. Pediatric Patients Initial Review Criteria ○ Patient must have hemoglobin < 10 g/dL, transferrin saturation ≥ 20% and serum ferritin ≥ 100ng/mL. ○ Patient must have lab data submitted within 2 months of PA submission. Continuation of Therapy ○ Patient must have hemoglobin ≤ 12 g/dL, transferrin saturation ≥ 20% and serum ferritin ≥ 100ng/mL. ○ Patient must have lab data submitted within 2 months of PA submission.
	Anemia associated with chronic kidney disease if patient is on dialysis	Adult Patients Initial Review Therapy ○ Patient must have hemoglobin < 10g/dL, transferrin saturation ≥ 20% and serum ferritin ≥ 100ng/mL.



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Anemia associated with	Initial Therapy	
chemotherapy	 Patient has no existing history of iron or folate deficiency, hemolysis, 	
	or gastrointestinal bleeding.	
	o Patient must have hemoglobin < 10 g/dL, transferrin saturation ≥ 20%	
	and serum ferritin ≥ 100ng/mL.	
	 Must be on or initiating chemotherapy (minimum of 2 months). 	
	Continuation of Therapy	
	 Patient has no existing history of iron or folate deficiency, hemolysis, 	
	or gastrointestinal bleeding.	
	 Patient must have hemoglobin < 10 g/dL or lowest level sufficient to 	
	avoid transfusion.	
	o Patient must have transferrin saturation ≥ 20% and serum ferritin ≥	
	100ng/mL.	
Anemia associated with	Initial Therapy	
Zidovudine in HIV therapy	 Patient has no existing history of iron or folate deficiency, hemolysis, 	
	or gastrointestinal bleeding.	
	 Patient must be receiving Zidovudine ≤ 4200 mg/week and have 	
	serum erythropoietin levels ≤ 500 mUnits/mL.	
	o Patient must have transferrin saturation ≥ 20% and serum ferritin ≥	
	100ng/mL.	
	Continuation of Therapy	
	 Patient must be receiving Zidovudine given at ≤ 4200 mg/week and 	
	have serum erythropoietin levels ≤ 500 mUnits/mL.	
	o Patient must have transferrin saturation $\geq 20\%$ and serum ferritin \geq	
	100ng/mL.	
	o Withhold if hemoglobin >12 g/dL, resume at a lower dose when	
	hemoglobin <11 g/dL.	
To reduce the need for	Patient must be unwilling to donate blood.	
allogenic blood	○ Patient must have hemoglobin > 10 and ≤ 13 g/dL.	
transfusions in anemic	 Patient must be receiving iron supplementation. 	
patients scheduled to	 Approve no more than 15 doses. 	
undergo elective, non-		
cardiac, nonvascular		
surgery		

DOSING AND ADMINISTRATION:

• Refer to product labeling https://www.accessdata.fda.gov/scripts/cder/daf/

Supplemental iron therapy is recommended for all patients whose serum ferritin is below 100 mcg/L or whose serum transferrin saturation is below 20%.

Erythropoiesis Stimulating Agents are not intended for patients who require immediate correction of severe anemia. Mircerna may remove the need for maintenance transfusions but is not a substitute for emergency transfusion or treatment of other causes of anemia, such as iron deficiency, underlying infectious, inflammatory, or malignant processes, occult blood loss, underlying hematologic diseases, folic acid, vitamin B-12 deficiency, or hemolysis.