

Division: Pharmacy Policy	Subject: State of Florida's Agency for Health Care Administration's Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	August 18, 2021 February 21, 2022

Erythropoiesis Stimulating Agents

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

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

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 RetacritTM) 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 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 lab data submitted within 2 months of PA submission. Continuation of Therapy ○ 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
	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 ≤ 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.
		 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 chemotherapy	Initial Therapy ○ Patient has no existing history of iron or folate deficiency, hemolysis, or gastrointestinal bleeding. ○ 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. ○ Patient must have transferrin saturation ≥ 20% and serum ferritin ≥ 100ng/mL.
		Toong mL.
Retacrit TM	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 hemoglobin ≤ 10 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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	Padiatria Patianta
	<u>Pediatric Patients</u>
	Initial Review Criteria
	• Patient must have hemoglobin < 10 g/dL, transferrin saturation \geq 20% and array familia > 100 m/mL
	20% and serum ferritin \geq 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 $\geq 20\%$
	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	• Patient must have hemoglobin < $10g/dL$, transferrin saturation $\ge 20\%$
	and serum ferritin \geq 100ng/mL.
	• Patient must have lab data submitted within 2 months of PA
	submission.
	Continuation of Therapy
	• Patient must have hemoglobin ≤ 11 g/dL, transferrin saturation $\geq 20\%$
	and serum ferritin \geq 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 \geq
	20% and serum ferritin ≥ 100 mg/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 $\geq 20\%$
	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,
15	or gastrointestinal bleeding.
	• Patient must have hemoglobin < 10 g/dL, transferrin saturation $\ge 20\%$
	and serum ferritin ≥ 100 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.
	• Patient must have transferrin saturation $\geq 20\%$ and serum ferritin \geq
	100ng/mL.
Anemia associated with	Initial Therapy
Zidovudine in HIV therapy	• Patient has no existing history of iron or folate deficiency, hemolysis,
2. dovudine in my dierapy	or gastrointestinal bleeding.
	or gustronnesting bround.



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	To reduce the need for allogenic blood transfusions in anemic patients scheduled to undergo elective, non- cardiac, 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. Patient must have transferrin saturation ≥ 20% and serum ferritin ≥ 100ng/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 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 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 < 10 g/dL, transferrin saturation ≥ 20% and serum ferritin ≥ 100ng/mL. ○ 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 hemoglobin
		submission. Continuation of Therapy



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	• Patient must have hemoglobin ≤ 11 g/dL, transferrin saturation $\geq 20\%$
	and serum ferritin \geq 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 \geq
	20% and serum ferritin \geq 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 $\geq 20\%$
	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,
	or gastrointestinal bleeding.
	• Patient must have hemoglobin < 10 g/dL, transferrin saturation \ge 20%
	and serum ferritin \geq 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.
	• Patient must have transferrin saturation \geq 20% and serum ferritin \geq
A	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 $\leq 4200 \text{ mg/week}$ and have
	serum erythropoietin levels \leq 500 mUnits/mL.
	• Patient must have transferrin saturation $\geq 20\%$ and serum ferritin $\geq 100 \text{ m/m}$
	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 $\geq 20\%$ and serum ferritin $\geq 100 \text{ ng/mL}$
	100ng/mL. Withhold if homoslohin $>12 \text{ g/dL}$ resume at a lower does when
	• Withhold if hemoglobin >12 g/dL, resume at a lower dose when hemoglobin ≤ 11 g/dL
To reduce the need for	hemoglobin <11 g/dL.
To reduce the need for allogenic blood	 Patient must be unwilling to donate blood. Patient must have hemoglobin > 10 and ≤ 13 g/dL.
transfusions in anemic	
patients scheduled to	 Patient must be receiving iron supplementation. Approve no more than 15 doses.
undergo elective, non-	• Approve no more than 15 doses.
cardiac, nonvascular	
surgery	



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Mircera®	Anemia associated with	Adult Patients
Mintera	chronic kidney disease if	Initial Review Therapy
	patient is not on dialysis	• Patient must have hemoglobin < 10 g/dL, transferrin saturation ≥ 20 %
		and serum ferritin ≥ 100 ng/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 $\geq 20\%$
		and serum ferritin ≥ 100 mL.
		 Patient must have lab data submitted within 2 months of PA submission.
		submission.
		Pediatric Patients
		Initial Review Criteria
		• Patient must have hemoglobin < 10 g/dL, transferrin saturation \geq
		20% and serum ferritin \geq 100ng/mL.
		• Patient must have lab data submitted within 2 months of PA
		submission.
		Continuation of Therapy
		• Patient must have hemoglobin $\leq 12 \text{ g/dL}$, transferrin saturation $\geq 20\%$
		 and serum ferritin ≥ 100ng/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	• Patient must have hemoglobin $< 10g/dL$, transferrin saturation $\ge 20\%$
		and serum ferritin ≥ 100 ng/mL.
		• Patient must have lab data submitted within 2 months of PA
		submission.
		Continuation of Therapy
		• Patient must have hemoglobin ≤ 11 g/dL, transferrin saturation $\geq 20\%$ and serum ferritin ≥ 100 mg/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 \geq
		20% and serum ferritin ≥ 100ng/mL. o Patient must have lab data submitted within 2 months of PA
		• Patient must have lab data submitted within 2 months of PA submission.
		Continuation of Therapy
		• 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.
	Pediatric patients on	Initial Review Criteria • Patient must be 5 to 17 years of age.
	dialysis	• 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.
	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. 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. Patient must have transferrin saturation ≥ 20% and serum ferritin ≥ 100ng/mL.
Anemia associated with Zidovudine in HIV therapy	 Initial 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. 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 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. 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.
To reduce the need for allogenic blood transfusions in anemic patients scheduled to undergo elective, non- cardiac, nonvascular surgery	 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.

DOSING AND ADMINISTRATION:

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

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.