Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	August 18, 2021 February 21, 2022; January 24, 2024, March 18, 2025

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), Vafseo® (vadadustat)

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** 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** 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. *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 ≤ 12 g/dL, transferrin saturation ≥ 20% and serum ferritin ≥ 100ng/mL. o 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** 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** o Patient must have hemoglobin ≤ 11 g/dL, transferrin saturation ≥ 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 ≤ 12 g/dL, transferrin saturation ≥ 20% and serum ferritin ≥ 100ng/mL. o Patient must have lab data submitted within 2 months of PA submission.
	Anemia associated with chemotherapy	**Initial Therapy** 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 ≥ 100ng/mL. o 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. 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.
Retacrit®	Anemia associated with chronic kidney disease if patient is **not on dialysis**	*Adult Patients* **Initial Review Therapy** 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** 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.

		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 ≤ 12 g/dL, transferrin saturation ≥ 20% and serum ferritin ≥ 100ng/mL. o 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** 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** o Patient must have hemoglobin ≤ 11 g/dL, transferrin saturation ≥ 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 ≤ 12 g/dL, transferrin saturation ≥ 20% and serum ferritin ≥ 100ng/mL. o Patient must have lab data submitted within 2 months of PA submission.
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	Anemia associated with Zidovudine in HIV therapy	**Initial Therapy** o Patient has no existing history of iron or folate deficiency, hemolysis, or gastrointestinal bleeding.

		○ 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.
	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.
Epogen®	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. ○ 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.
	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 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.

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Mircera®	Anemia associated with chronic kidney disease if patient is **not on dialysis**	*Adult Patients* **Initial Review Therapy** 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** 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. *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 ≤ 12 g/dL, transferrin saturation ≥ 20% and serum ferritin ≥ 100ng/mL. o 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** 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** o Patient must have hemoglobin ≤ 11 g/dL, transferrin saturation ≥ 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 ≤ 12 g/dL, transferrin saturation ≥ 20% and serum ferritin ≥ 100ng/mL. o Patient must have lab data submitted within 2 months of PA submission.
	Pediatric patients on dialysis	**Initial Review Criteria** 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. ○ 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** 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 ≥ 100ng/mL. o 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. 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 Zidovudine in HIV therapy	**Initial Therapy** o Patient has no existing history of iron or folate deficiency, hemolysis, or gastrointestinal bleeding. o 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** o Patient must be receiving Zidovudine given at ≤ 4200 mg/week and have serum erythropoietin levels ≤ 500 mUnits/mL. o Patient must have transferrin saturation ≥ 20% and serum ferritin ≥ 100ng/mL. o 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	o Patient must be unwilling to donate blood. o Patient must have hemoglobin > 10 and ≤ 13 g/dL. o Patient must be receiving iron supplementation. o Approve no more than 15 doses.
Vafseo®	Anemia associated with chronic kidney disease if patient is **on dialysis**	*Adult Patients* **Initial Review Therapy** o Must be on dialysis (minimum of 3 months). 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** o Patient must have hemoglobin ≤ 11 g/dL, transferrin saturation ≥ 20% and serum ferritin ≥ 100ng/mL. o Patient must have lab data submitted within 2 months of PA submission.

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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.