

Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	August 18, 2021 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	<p><u>Adult Patients</u></p> <p>Initial Review Therapy</p> <ul style="list-style-type: none"> ○ 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. <p>Continuation of Therapy</p> <ul style="list-style-type: none"> ○ 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. <p><u>Pediatric Patients</u></p> <p>Initial Review Criteria</p> <ul style="list-style-type: none"> ○ 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. <p>Continuation of Therapy</p> <ul style="list-style-type: none"> ○ 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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	<p>Anemia associated with chronic kidney disease if patient is on dialysis</p>	<p><u>Adult Patients</u> Initial Review Therapy</p> <ul style="list-style-type: none"> ○ 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. <p>Continuation of Therapy</p> <ul style="list-style-type: none"> ○ 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. <p><u>Pediatric Patients</u> Initial Review Criteria</p> <ul style="list-style-type: none"> ○ 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. <p>Continuation of Therapy</p> <ul style="list-style-type: none"> ○ 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.
	<p>Anemia associated with chemotherapy</p>	<p>Initial Therapy</p> <ul style="list-style-type: none"> ○ 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). <p>Continuation of Therapy</p> <ul style="list-style-type: none"> ○ 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.
<p>Retacrit®</p>	<p>Anemia associated with chronic kidney disease if patient is not on dialysis</p>	<p><u>Adult Patients</u> Initial Review Therapy</p> <ul style="list-style-type: none"> ○ 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. <p>Continuation of Therapy</p> <ul style="list-style-type: none"> ○ 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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	<p><u><i>Pediatric Patients</i></u> Initial Review Criteria</p> <ul style="list-style-type: none"> ○ 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. <p>Continuation of Therapy</p> <ul style="list-style-type: none"> ○ 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	<p><u><i>Adult Patients</i></u> Initial Review Therapy</p> <ul style="list-style-type: none"> ○ 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. <p>Continuation of Therapy</p> <ul style="list-style-type: none"> ○ 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. <p><u><i>Pediatric Patients</i></u> Initial Review Criteria</p> <ul style="list-style-type: none"> ○ 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. <p>Continuation of Therapy</p> <ul style="list-style-type: none"> ○ 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	<p>Initial Therapy</p> <ul style="list-style-type: none"> ○ 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). <p>Continuation of Therapy</p> <ul style="list-style-type: none"> ○ 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	<p>Initial Therapy</p> <ul style="list-style-type: none"> ○ 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, non-cardiac, nonvascular surgery	<ul style="list-style-type: none"> ○ Patient must be unwilling to donate blood. ○ Patient must have hemoglobin $>$ 10 and \leq 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	<p><u>Adult Patients</u></p> <p>Initial Review Therapy</p> <ul style="list-style-type: none"> ○ Patient must have hemoglobin $<$ 10g/dL, transferrin saturation \geq 20% and serum ferritin \geq 100ng/mL. ○ Patient must have lab data submitted within 2 months of PA submission. <p>Continuation of Therapy</p> <ul style="list-style-type: none"> ○ Patient must have hemoglobin \leq 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. <p><u>Pediatric Patients</u></p> <p>Initial Review Criteria</p> <ul style="list-style-type: none"> ○ 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. <p>Continuation of Therapy</p> <ul style="list-style-type: none"> ○ Patient must have hemoglobin \leq 12 g/dL, transferrin saturation \geq 20% and serum ferritin \geq 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	<p><u>Adult Patients</u></p> <p>Initial Review Therapy</p> <ul style="list-style-type: none"> ○ Patient must have hemoglobin $<$ 10g/dL, transferrin saturation \geq 20% and serum ferritin \geq 100ng/mL. ○ Patient must have lab data submitted within 2 months of PA submission. <p>Continuation of Therapy</p>

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	<ul style="list-style-type: none"> ○ 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. <p><u>Pediatric Patients</u> Initial Review Criteria</p> <ul style="list-style-type: none"> ○ Patient must have hemoglobin < 10 g/dL, transferrin saturation $\geq 20\%$ and serum ferritin ≥ 100ng/mL. ○ Patient must have lab data submitted within 2 months of PA submission. <p>Continuation of Therapy</p> <ul style="list-style-type: none"> ○ Patient must have hemoglobin ≤ 12 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 chemotherapy	<p>Initial Therapy</p> <ul style="list-style-type: none"> ○ Patient has no existing history of iron or folate deficiency, hemolysis, or gastrointestinal bleeding. ○ Patient must have hemoglobin < 10 g/dL, transferrin saturation $\geq 20\%$ and serum ferritin ≥ 100ng/mL. ○ Must be on or initiating chemotherapy (minimum of 2 months). <p>Continuation of Therapy</p> <ul style="list-style-type: none"> ○ 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 ≥ 100ng/mL.
Anemia associated with Zidovudine in HIV therapy	<p>Initial Therapy</p> <ul style="list-style-type: none"> ○ 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 $\geq 20\%$ and serum ferritin ≥ 100ng/mL. <p>Continuation of Therapy</p> <ul style="list-style-type: none"> ○ 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 ≥ 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	<ul style="list-style-type: none"> ○ 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	<p><u>Adult Patients</u></p> <p>Initial Review Therapy</p> <ul style="list-style-type: none"> ○ 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. <p>Continuation of Therapy</p> <ul style="list-style-type: none"> ○ 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. <p><u>Pediatric Patients</u></p> <p>Initial Review Criteria</p> <ul style="list-style-type: none"> ○ 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. <p>Continuation of Therapy</p> <ul style="list-style-type: none"> ○ 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	<p><u>Adult Patients</u></p> <p>Initial Review Therapy</p> <ul style="list-style-type: none"> ○ 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. <p>Continuation of Therapy</p> <ul style="list-style-type: none"> ○ 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. <p><u>Pediatric Patients</u></p> <p>Initial Review Criteria</p> <ul style="list-style-type: none"> ○ 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. <p>Continuation of Therapy</p> <ul style="list-style-type: none"> ○ 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.
	Pediatric patients on dialysis	<p>Initial Review Criteria</p> <ul style="list-style-type: none"> ○ Patient must be 5 to 17 years of age.

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Procrit®	Anemia associated with chronic kidney disease if patient is not on dialysis	<p><u>Adult Patients</u> Initial Review Therapy</p> <ul style="list-style-type: none"> ○ 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. <p>Continuation of Therapy</p> <ul style="list-style-type: none"> ○ 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. <p><u>Pediatric Patients</u> Initial Review Criteria</p> <ul style="list-style-type: none"> ○ 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. <p>Continuation of Therapy</p> <ul style="list-style-type: none"> ○ 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	<p><u>Adult Patients</u> Initial Review Therapy</p> <ul style="list-style-type: none"> ○ 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. <p>Continuation of Therapy</p> <ul style="list-style-type: none"> ○ 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. <p><u>Pediatric Patients</u> Initial Review Criteria</p> <ul style="list-style-type: none"> ○ 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. <p>Continuation of Therapy</p> <ul style="list-style-type: none"> ○ 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 chemotherapy	<p>Initial Therapy</p> <ul style="list-style-type: none"> ○ 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). <p>Continuation of Therapy</p> <ul style="list-style-type: none"> ○ 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	<p>Initial Therapy</p> <ul style="list-style-type: none"> ○ 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. <p>Continuation of Therapy</p> <ul style="list-style-type: none"> ○ 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	<ul style="list-style-type: none"> ○ 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 <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.