



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

	<p>Anemia associated with chronic kidney disease if patient is <b>on dialysis</b></p>	<p><u>Adult Patients</u>  <b>Initial Review Therapy</b></p> <ul style="list-style-type: none"> <li>○ Patient must have hemoglobin &lt; 10g/dL, transferrin saturation ≥ 20% and serum ferritin ≥ 100ng/mL.</li> <li>○ Patient must have lab data submitted within 2 months of PA submission.</li> </ul> <p><b>Continuation of Therapy</b></p> <ul style="list-style-type: none"> <li>○ Patient must have hemoglobin ≤ 11 g/dL, transferrin saturation ≥ 20% and serum ferritin ≥ 100ng/mL.</li> <li>○ Patient must have lab data submitted within 2 months of PA submission.</li> </ul> <p><u>Pediatric Patients</u>  <b>Initial Review Criteria</b></p> <ul style="list-style-type: none"> <li>○ Patient must have hemoglobin &lt; 10 g/dL, transferrin saturation ≥ 20% and serum ferritin ≥ 100ng/mL.</li> <li>○ Patient must have lab data submitted within 2 months of PA submission.</li> </ul> <p><b>Continuation of Therapy</b></p> <ul style="list-style-type: none"> <li>○ Patient must have hemoglobin ≤ 12 g/dL, transferrin saturation ≥ 20% and serum ferritin ≥ 100ng/mL.</li> <li>○ Patient must have lab data submitted within 2 months of PA submission.</li> </ul>
	<p>Anemia associated with chemotherapy</p>	<p><b>Initial Therapy</b></p> <ul style="list-style-type: none"> <li>○ Patient has no existing history of iron or folate deficiency, hemolysis, or gastrointestinal bleeding.</li> <li>○ Patient must have hemoglobin &lt; 10 g/dL, transferrin saturation ≥ 20% and serum ferritin ≥ 100ng/mL.</li> <li>○ Must be on or initiating chemotherapy (minimum of 2 months).</li> </ul> <p><b>Continuation of Therapy</b></p> <ul style="list-style-type: none"> <li>○ Patient has no existing history of iron or folate deficiency, hemolysis, or gastrointestinal bleeding.</li> <li>○ Patient must have hemoglobin &lt; 10 g/dL or lowest level sufficient to avoid transfusion.</li> <li>○ Patient must have transferrin saturation ≥ 20% and serum ferritin ≥ 100ng/mL.</li> </ul>
<p><b>Retacrit™</b></p>	<p>Anemia associated with chronic kidney disease if patient is <b>not on dialysis</b></p>	<p><u>Adult Patients</u>  <b>Initial Review Therapy</b></p> <ul style="list-style-type: none"> <li>○ Patient must have hemoglobin &lt; 10g/dL, transferrin saturation ≥ 20% and serum ferritin ≥ 100ng/mL.</li> <li>○ Patient must have lab data submitted within 2 months of PA submission.</li> </ul> <p><b>Continuation of Therapy</b></p> <ul style="list-style-type: none"> <li>○ Patient must have hemoglobin ≤ 10 g/dL, transferrin saturation ≥ 20% and serum ferritin ≥ 100ng/mL.</li> <li>○ Patient must have lab data submitted within 2 months of PA submission.</li> </ul>

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	<p><u>Pediatric Patients</u></p> <p><b>Initial Review Criteria</b></p> <ul style="list-style-type: none"> <li>○ Patient must have hemoglobin &lt; 10 g/dL, transferrin saturation ≥ 20% and serum ferritin ≥ 100ng/mL.</li> <li>○ Patient must have lab data submitted within 2 months of PA submission.</li> </ul> <p><b>Continuation of Therapy</b></p> <ul style="list-style-type: none"> <li>○ Patient must have hemoglobin ≤ 12 g/dL, transferrin saturation ≥ 20% and serum ferritin ≥ 100ng/mL.</li> <li>○ Patient must have lab data submitted within 2 months of PA submission.</li> </ul>
Anemia associated with chronic kidney disease if patient is <b>on dialysis</b>	<p><u>Adult Patients</u></p> <p><b>Initial Review Therapy</b></p> <ul style="list-style-type: none"> <li>○ Patient must have hemoglobin &lt; 10g/dL, transferrin saturation ≥ 20% and serum ferritin ≥ 100ng/mL.</li> <li>○ Patient must have lab data submitted within 2 months of PA submission.</li> </ul> <p><b>Continuation of Therapy</b></p> <ul style="list-style-type: none"> <li>○ Patient must have hemoglobin ≤ 11 g/dL, transferrin saturation ≥ 20% and serum ferritin ≥ 100ng/mL.</li> <li>○ Patient must have lab data submitted within 2 months of PA submission.</li> </ul>
	<p><u>Pediatric Patients</u></p> <p><b>Initial Review Criteria</b></p> <ul style="list-style-type: none"> <li>○ Patient must have hemoglobin &lt; 10 g/dL, transferrin saturation ≥ 20% and serum ferritin ≥ 100ng/mL.</li> <li>○ Patient must have lab data submitted within 2 months of PA submission.</li> </ul> <p><b>Continuation of Therapy</b></p> <ul style="list-style-type: none"> <li>○ Patient must have hemoglobin ≤ 12 g/dL, transferrin saturation ≥ 20% and serum ferritin ≥ 100ng/mL.</li> <li>○ Patient must have lab data submitted within 2 months of PA submission.</li> </ul>
Anemia associated with chemotherapy	<p><b>Initial Therapy</b></p> <ul style="list-style-type: none"> <li>○ Patient has no existing history of iron or folate deficiency, hemolysis, or gastrointestinal bleeding.</li> <li>○ Patient must have hemoglobin &lt; 10 g/dL, transferrin saturation ≥ 20% and serum ferritin ≥ 100ng/mL.</li> <li>○ Must be on or initiating chemotherapy (minimum of 2 months).</li> </ul> <p><b>Continuation of Therapy</b></p> <ul style="list-style-type: none"> <li>○ Patient has no existing history of iron or folate deficiency, hemolysis, or gastrointestinal bleeding.</li> <li>○ Patient must have hemoglobin &lt; 10 g/dL or lowest level sufficient to avoid transfusion.</li> <li>○ Patient must have transferrin saturation ≥ 20% and serum ferritin ≥ 100ng/mL.</li> </ul>
Anemia associated with Zidovudine in HIV therapy	<p><b>Initial Therapy</b></p> <ul style="list-style-type: none"> <li>○ Patient has no existing history of iron or folate deficiency, hemolysis, or gastrointestinal bleeding.</li> </ul>

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		<ul style="list-style-type: none"> <li>○ Patient must be receiving Zidovudine <math>\leq</math> 4200 mg/week with serum erythropoietin levels <math>\leq</math> 500 mUnits/mL.</li> <li>○ Patient must have transferrin saturation <math>\geq</math> 20% and serum ferritin <math>\geq</math> 100ng/mL.</li> </ul> <p><b>Continuation of Therapy</b></p> <ul style="list-style-type: none"> <li>○ Patient must be receiving Zidovudine given at <math>\leq</math> 4200 mg/week and have serum erythropoietin levels <math>\leq</math> 500 mUnits/mL.</li> <li>○ Patient must have transferrin saturation <math>\geq</math> 20% and serum ferritin <math>\geq</math> 100ng/mL.</li> <li>○ Withhold if hemoglobin <math>&gt;</math>12 g/dL, resume at a lower dose when hemoglobin <math>&lt;</math>11 g/dL.</li> </ul>
	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"> <li>○ Patient must be unwilling to donate blood.</li> <li>○ Patient must have hemoglobin <math>&gt;</math> 10 and <math>\leq</math> 13 g/dL.</li> <li>○ Patient must be receiving iron supplementation.</li> <li>○ Approve no more than 15 doses.</li> </ul>

<b>Epogen<sup>®</sup></b>	Anemia associated with chronic kidney disease if patient is <b>not on dialysis</b>	<p><u>Adult Patients</u></p> <p><b>Initial Review Therapy</b></p> <ul style="list-style-type: none"> <li>○ Patient must have hemoglobin <math>&lt;</math> 10g/dL, transferrin saturation <math>\geq</math> 20% and serum ferritin <math>\geq</math> 100ng/mL.</li> <li>○ Patient must have lab data submitted within 2 months of PA submission.</li> </ul> <p><b>Continuation of Therapy</b></p> <ul style="list-style-type: none"> <li>○ Patient must have hemoglobin <math>\leq</math> 10 g/dL, transferrin saturation <math>\geq</math> 20% and serum ferritin <math>\geq</math> 100ng/mL.</li> <li>○ Patient must have lab data submitted within 2 months of PA submission.</li> </ul> <p><u>Pediatric Patients</u></p> <p><b>Initial Review Criteria</b></p> <ul style="list-style-type: none"> <li>○ Patient must have hemoglobin <math>&lt;</math> 10 g/dL, transferrin saturation <math>\geq</math> 20% and serum ferritin <math>\geq</math> 100ng/mL.</li> <li>○ Patient must have lab data submitted within 2 months of PA submission.</li> </ul> <p><b>Continuation of Therapy</b></p> <ul style="list-style-type: none"> <li>○ Patient must have hemoglobin <math>\leq</math> 12 g/dL, transferrin saturation <math>\geq</math> 20% and serum ferritin <math>\geq</math> 100ng/mL.</li> <li>○ Patient must have lab data submitted within 2 months of PA submission.</li> </ul>
	Anemia associated with chronic kidney disease if patient is <b>on dialysis</b>	<p><u>Adult Patients</u></p> <p><b>Initial Review Therapy</b></p> <ul style="list-style-type: none"> <li>○ Patient must have hemoglobin <math>&lt;</math> 10g/dL, transferrin saturation <math>\geq</math> 20% and serum ferritin <math>\geq</math> 100ng/mL.</li> <li>○ Patient must have lab data submitted within 2 months of PA submission.</li> </ul> <p><b>Continuation of Therapy</b></p>

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	<ul style="list-style-type: none"> <li>○ Patient must have hemoglobin <math>\leq 11</math> g/dL, transferrin saturation <math>\geq 20\%</math> and serum ferritin <math>\geq 100</math>ng/mL.</li> <li>○ Patient must have lab data submitted within 2 months of PA submission.</li> </ul> <p><u>Pediatric Patients</u></p> <p><b>Initial Review Criteria</b></p> <ul style="list-style-type: none"> <li>○ Patient must have hemoglobin <math>&lt; 10</math> g/dL, transferrin saturation <math>\geq 20\%</math> and serum ferritin <math>\geq 100</math>ng/mL.</li> <li>○ Patient must have lab data submitted within 2 months of PA submission.</li> </ul> <p><b>Continuation of Therapy</b></p> <ul style="list-style-type: none"> <li>○ Patient must have hemoglobin <math>\leq 12</math> g/dL, transferrin saturation <math>\geq 20\%</math> and serum ferritin <math>\geq 100</math>ng/mL.</li> <li>○ Patient must have lab data submitted within 2 months of PA submission.</li> </ul>
Anemia associated with chemotherapy	<p><b>Initial Therapy</b></p> <ul style="list-style-type: none"> <li>○ Patient has no existing history of iron or folate deficiency, hemolysis, or gastrointestinal bleeding.</li> <li>○ Patient must have hemoglobin <math>&lt; 10</math> g/dL, transferrin saturation <math>\geq 20\%</math> and serum ferritin <math>\geq 100</math>ng/mL.</li> <li>○ Must be on or initiating chemotherapy (minimum of 2 months).</li> </ul> <p><b>Continuation of Therapy</b></p> <ul style="list-style-type: none"> <li>○ Patient has no existing history of iron or folate deficiency, hemolysis, or gastrointestinal bleeding.</li> <li>○ Patient must have hemoglobin <math>&lt; 10</math> g/dL or lowest level sufficient to avoid transfusion.</li> <li>○ Patient must have transferrin saturation <math>\geq 20\%</math> and serum ferritin <math>\geq 100</math>ng/mL.</li> </ul>
Anemia associated with Zidovudine in HIV therapy	<p><b>Initial Therapy</b></p> <ul style="list-style-type: none"> <li>○ Patient has no existing history of iron or folate deficiency, hemolysis, or gastrointestinal bleeding.</li> <li>○ Patient must be receiving Zidovudine <math>\leq 4200</math> mg/week and have serum erythropoietin levels <math>\leq 500</math> mUnits/mL.</li> <li>○ Patient must have transferrin saturation <math>\geq 20\%</math> and serum ferritin <math>\geq 100</math>ng/mL.</li> </ul> <p><b>Continuation of Therapy</b></p> <ul style="list-style-type: none"> <li>○ Patient must be receiving Zidovudine given at <math>\leq 4200</math> mg/week and have serum erythropoietin levels <math>\leq 500</math> mUnits/mL.</li> <li>○ Patient must have transferrin saturation <math>\geq 20\%</math> and serum ferritin <math>\geq 100</math>ng/mL.</li> <li>○ Withhold if hemoglobin <math>&gt; 12</math> g/dL, resume at a lower dose when hemoglobin <math>&lt; 11</math> g/dL.</li> </ul>
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"> <li>○ Patient must be unwilling to donate blood.</li> <li>○ Patient must have hemoglobin <math>&gt; 10</math> and <math>\leq 13</math> g/dL.</li> <li>○ Patient must be receiving iron supplementation.</li> <li>○ Approve no more than 15 doses.</li> </ul>

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<b>Mircera<sup>®</sup></b>	Anemia associated with chronic kidney disease if patient is <b>not on dialysis</b>	<p><u>Adult Patients</u>  <b>Initial Review Therapy</b></p> <ul style="list-style-type: none"> <li>○ Patient must have hemoglobin &lt; 10g/dL, transferrin saturation ≥ 20% and serum ferritin ≥ 100ng/mL.</li> <li>○ Patient must have lab data submitted within 2 months of PA submission.</li> </ul> <p><b>Continuation of Therapy</b></p> <ul style="list-style-type: none"> <li>○ Patient must have hemoglobin ≤ 10 g/dL, transferrin saturation ≥ 20% and serum ferritin ≥ 100ng/mL.</li> <li>○ Patient must have lab data submitted within 2 months of PA submission.</li> </ul> <p><u>Pediatric Patients</u>  <b>Initial Review Criteria</b></p> <ul style="list-style-type: none"> <li>○ Patient must have hemoglobin &lt; 10 g/dL, transferrin saturation ≥ 20% and serum ferritin ≥ 100ng/mL.</li> <li>○ Patient must have lab data submitted within 2 months of PA submission.</li> </ul> <p><b>Continuation of Therapy</b></p> <ul style="list-style-type: none"> <li>○ Patient must have hemoglobin ≤ 12 g/dL, transferrin saturation ≥ 20% and serum ferritin ≥ 100ng/mL.</li> <li>○ Patient must have lab data submitted within 2 months of PA submission.</li> </ul>
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	Pediatric patients on dialysis	<p><b>Initial Review Criteria</b></p> <ul style="list-style-type: none"> <li>○ Patient must be 5 to 17 years of age.</li> </ul>

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		<ul style="list-style-type: none"> <li>○ Patient must be converting from another erythropoiesis-stimulating agent once hemoglobin is stable.</li> </ul>
<b>Procrit<sup>®</sup></b>	Anemia associated with chronic kidney disease if patient is <b>not on dialysis</b>	<p><u>Adult Patients</u>  <b>Initial Review Therapy</b></p> <ul style="list-style-type: none"> <li>○ Patient must have hemoglobin &lt; 10g/dL, transferrin saturation ≥ 20% and serum ferritin ≥ 100ng/mL.</li> <li>○ Patient must have lab data submitted within 2 months of PA submission.</li> </ul> <p><b>Continuation of Therapy</b></p> <ul style="list-style-type: none"> <li>○ Patient must have hemoglobin ≤ 10 g/dL, transferrin saturation ≥ 20% and serum ferritin ≥ 100ng/mL.</li> <li>○ Patient must have lab data submitted within 2 months of PA submission.</li> </ul> <p><u>Pediatric Patients</u>  <b>Initial Review Criteria</b></p> <ul style="list-style-type: none"> <li>○ Patient must have hemoglobin &lt; 10 g/dL, transferrin saturation ≥ 20% and serum ferritin ≥ 100ng/mL.</li> <li>○ Patient must have lab data submitted within 2 months of PA submission.</li> </ul> <p><b>Continuation of Therapy</b></p> <ul style="list-style-type: none"> <li>○ Patient must have hemoglobin ≤ 12 g/dL, transferrin saturation ≥ 20% and serum ferritin ≥ 100ng/mL.</li> <li>○ Patient must have lab data submitted within 2 months of PA submission.</li> </ul>
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Anemia associated with chemotherapy	<p><b>Initial Therapy</b></p> <ul style="list-style-type: none"> <li>○ Patient has no existing history of iron or folate deficiency, hemolysis, or gastrointestinal bleeding.</li> <li>○ Patient must have hemoglobin &lt; 10 g/dL, transferrin saturation ≥ 20% and serum ferritin ≥ 100ng/mL.</li> <li>○ Must be on or initiating chemotherapy (minimum of 2 months).</li> </ul> <p><b>Continuation of Therapy</b></p> <ul style="list-style-type: none"> <li>○ Patient has no existing history of iron or folate deficiency, hemolysis, or gastrointestinal bleeding.</li> <li>○ Patient must have hemoglobin &lt; 10 g/dL or lowest level sufficient to avoid transfusion.</li> <li>○ Patient must have transferrin saturation ≥ 20% and serum ferritin ≥ 100ng/mL.</li> </ul>
Anemia associated with Zidovudine in HIV therapy	<p><b>Initial Therapy</b></p> <ul style="list-style-type: none"> <li>○ Patient has no existing history of iron or folate deficiency, hemolysis, or gastrointestinal bleeding.</li> <li>○ Patient must be receiving Zidovudine ≤ 4200 mg/week and have serum erythropoietin levels ≤ 500 mUnits/mL.</li> <li>○ Patient must have transferrin saturation ≥ 20% and serum ferritin ≥ 100ng/mL.</li> </ul> <p><b>Continuation of Therapy</b></p> <ul style="list-style-type: none"> <li>○ Patient must be receiving Zidovudine given at ≤ 4200 mg/week and have serum erythropoietin levels ≤ 500 mUnits/mL.</li> <li>○ Patient must have transferrin saturation ≥ 20% and serum ferritin ≥ 100ng/mL.</li> <li>○ Withhold if hemoglobin &gt;12 g/dL, resume at a lower dose when hemoglobin &lt;11 g/dL.</li> </ul>
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"> <li>○ Patient must be unwilling to donate blood.</li> <li>○ Patient must have hemoglobin &gt; 10 and ≤ 13 g/dL.</li> <li>○ Patient must be receiving iron supplementation.</li> <li>○ Approve no more than 15 doses.</li> </ul>

**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.*