



# Erythropoietins Prior Authorization Program Summary

## POLICY REVIEW CYCLE

**Effective Date**  
11-01-2025

**Date of Origin**

## POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Aranesp albumin free	darbepoetin alfa soln inj ; darbepoetin alfa soln prefilled syringe	10 MCG/0.4ML ; 100 MCG/0.5ML ; 100 MCG/ML ; 150 MCG/0.3ML ; 200 MCG/0.4ML ; 200 MCG/ML ; 25 MCG/0.42ML ; 25 MCG/ML ; 300 MCG/0.6ML ; 40 MCG/0.4ML ; 40 MCG/ML ; 500 MCG/ML ; 60 MCG/0.3ML ; 60 MCG/ML	M ; N ; O ; Y	N		
Epogen ; Procrit	epoetin alfa inj	10000 UNIT/ML ; 2000 UNIT/ML ; 20000 UNIT/ML ; 3000 UNIT/ML ; 4000 UNIT/ML ; 40000 UNIT/ML	M ; N ; O ; Y	N		
Retacrit	epoetin alfa-epbx inj	10000 UNIT/ML ; 2000 UNIT/ML ; 20000 UNIT/2ML ; 20000 UNIT/ML ; 3000 UNIT/ML ; 4000 UNIT/ML ; 40000 UNIT/ML	M ; N ; O ; Y	N		
Mircera	methoxy peg-epoetin beta soln prefilled syr	100 MCG/0.3ML ; 120 MCG/0.3ML ; 150 MCG/0.3ML ; 200 MCG/0.3ML ; 30 MCG/0.3ML ; 50 MCG/0.3ML ; 75 MCG/0.3ML	M ; N ; O ; Y	N		

## CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Aranesp albumin free	darbepoetin alfa soln inj ; darbepoetin alfa soln prefilled syringe	10 MCG/0.4ML ; 100 MCG/0.5ML ; 100 MCG/ML ; 150 MCG/0.3ML ; 200 MCG/0.4ML ; 200 MCG/ML ; 25 MCG/0.42ML ; 25 MCG/ML ; 300 MCG/0.6ML ; 40 MCG/0.4ML ; 40 MCG/ML ; 500 MCG/ML ; 60 MCG/0.3ML ; 60 MCG/ML	IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Epogen ; Procrit	epoetin alfa inj	10000 UNIT/ML ; 2000 UNIT/ML ; 20000 UNIT/ML ; 3000 UNIT/ML ; 4000 UNIT/ML ; 40000 UNIT/ML	IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Mircera	methoxy peg-epoetin beta soln prefilled syr	100 MCG/0.3ML ; 120 MCG/0.3ML ; 150 MCG/0.3ML ; 200 MCG/0.3ML ; 30 MCG/0.3ML ; 50 MCG/0.3ML ; 75 MCG/0.3ML	IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Retacrit	epoetin alfa-epbx inj	10000 UNIT/ML ; 2000 UNIT/ML ; 20000 UNIT/2ML ; 20000 UNIT/ML ; 3000 UNIT/ML ; 4000 UNIT/ML ; 40000 UNIT/ML	IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods

## PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	<p><b>Target Agent(s)</b> will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> <li>1. Prior to starting the requested agent, the patient's iron stores were evaluated, and blood ferritin found to be at least 100 ng/mL (nanograms per milliliter) OR transferrin saturation found to be at least 20% <b>AND</b></li> <li>2. Iron stores will be maintained before starting and while using ESA therapy <b>AND</b></li> <li>3. Blood pressure will be adequately controlled and closely monitored before and during ESA therapy <b>AND</b></li> <li>4. The ESA dose is the lowest dose that will gradually increase Hgb concentration to the lowest level sufficient to avoid the need for red blood cell (RBC) transfusion <b>AND</b></li> <li>5. ONE of the following: <ol style="list-style-type: none"> <li>A. The requested agent is Epoetin alfa (Epogen, Procrit) OR Epoetin alfa-epbx (Retacrit) and the patient will be using the requested agent for ONE of the following: <ol style="list-style-type: none"> <li>1. Anemia associated with chronic kidney disease (including end-stage renal disease—ESRD) and: <ol style="list-style-type: none"> <li>A. The patient has a Hgb level of less than 11 g/dL (or less than 10 g/dL for patients initiating ESA therapy) and the requested agent will be used to reduce the need for red cell transfusions <b>OR</b></li> <li>2. Anemia in cancer patients with metastatic non-myeloid malignancies AND all of the following: <ol style="list-style-type: none"> <li>A. The patient is undergoing myelosuppressive chemotherapy <b>AND</b></li> <li>B. Anemia is caused by myelosuppressive chemotherapy <b>AND</b></li> <li>C. Anemia is not due to other factors, e.g., iron or folate deficiencies, hemolysis, gastrointestinal bleeding, or underlying hemolytic disease (e.g., sickle cell anemia, thalassemia, porphyria) <b>AND</b></li> <li>D. The anticipated outcome of myelosuppressive therapy is not cure <b>AND</b></li> </ol> </li> </ol> </li> </ol> </li> </ol> </li> </ol>

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	<ul style="list-style-type: none"> <li>E. The patient has a Hgb level of 12 g/dL or less (or approaching or has fallen below 10 g/dL for patients initiating ESA therapy) <b>OR</b></li> <li>3. Anemia related to therapy with AZT (zidovudine) in HIV-infected (human immunodeficiency virus) patients and: <ul style="list-style-type: none"> <li>A. The patient's endogenous serum erythropoietin level is less than or equal to 500 mUnits/mL <b>OR</b></li> </ul> </li> <li>4. To reduce the need for allogeneic blood transfusion in pre-operative surgery patients AND all of the following: <ul style="list-style-type: none"> <li>A. The patient is scheduled for elective, non-cardiac, non-vascular surgery <b>AND</b></li> <li>B. Hgb is less than 13 g/dL <b>AND</b></li> <li>C. The patient is not a candidate for autologous blood transfusion <b>AND</b></li> <li>D. There is a high risk for significant perioperative blood loss <b>OR</b></li> </ul> </li> <li>5. Anemia in patients with myelodysplastic syndromes to reduce transfusion dependency <b>OR</b></li> <li>6. Anemia associated with Hepatitis C AND all of the following: <ul style="list-style-type: none"> <li>A. The patient is being treated with the combination of ribavirin and interferon alfa or ribavirin and peginterferon <b>AND</b></li> <li>B. Other causes of anemia have been ruled out <b>AND</b></li> <li>C. The patient has failed to respond (i.e., severe anemia) within two weeks after reducing the dose of Ribavirin by 200 mg/day from the initial dose (NOTE: Use of erythropoietin may be considered prior to dose reduction for the following: 1) documented evidence of cirrhosis, or 2) post liver transplant, or 3) HIV co-infection) <b>AND</b></li> <li>D. Hgb is less than 10 gm/dL, or patient is symptomatic and has Hgb is less than 11 g/dL <b>OR</b></li> </ul> </li> <li>B. The requested agent is Darbepoetin Alfa (Aranesp), and the patient will use the requested agent for ONE of the following: <ul style="list-style-type: none"> <li>1. Anemia Associated with chronic kidney disease (including end-stage renal disease—ESRD) and: <ul style="list-style-type: none"> <li>A. The patient has an Hgb level of less than 11 g/dL (or less than 10 g/dL for patients initiating ESA therapy) and the requested agent will be used to reduce the need for red cell transfusions <b>OR</b></li> </ul> </li> <li>2. Anemia in cancer patients with non-myeloid metastatic malignancies AND all of the following: <ul style="list-style-type: none"> <li>A. The patient is undergoing myelosuppressive chemotherapy <b>AND</b></li> <li>B. Anemia is caused by myelosuppressive chemotherapy <b>AND</b></li> <li>C. The anticipated outcome of myelosuppressive therapy is not cure <b>AND</b></li> <li>D. The patient has a Hgb level of 12 g/dL or less (or approaching or has fallen below 10 g/dL for patients initiating ESA therapy) <b>OR</b></li> </ul> </li> <li>3. Anemia in patients with myelodysplastic syndromes to reduce transfusion dependency <b>OR</b></li> </ul> </li> <li>C. The requested agent is Methoxy polyethylene glycol-epoetin beta (Mircera), and the patient will use the requested agent for: <ul style="list-style-type: none"> <li>1. Anemia associated with chronic kidney disease (including end-stage renal disease—ESRD) and: <ul style="list-style-type: none"> <li>A. The patient has an Hgb level of less than 11 g/dL (or less than 10 g/dL for patients initiating ESA therapy) and the requested agent will be used to reduce the need for red cell transfusions <b>OR</b></li> </ul> </li> </ul> </li> <li>D. The patient has another FDA labeled indication for the requested agent and route of administration AND the patient's hemoglobin level is within the FDA labeling for patients initiating ESA therapy or for patients stabilized on therapy for the requested indication <b>OR</b></li> <li>E. The patient has another indication that is supported in compendia for the requested agent and route of administration AND the patient's hemoglobin level is within the compendia recommended range for the requested indication for</li> </ul>

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	<p>patients initiating ESA therapy or for patients stabilized on therapy for the requested indication <b>AND</b></p> <ol style="list-style-type: none"> <li>6. The prescriber is a specialist in the area of the patient's diagnosis (e.g., nephrologist, oncologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis <b>AND</b></li> <li>7. The patient does NOT have any FDA labeled contraindications to the requested agent</li> </ol> <p><b>Compendia Allowed:</b> AHFS, or DrugDex 1, 2a, or 2b level of evidence, NCCN 1, 2a, or 2b recommended use</p> <p><b>Length of Approval</b></p> <p>BCBSOK: 36 months</p> <p>BCBSIL and BCBSMT: 12 months</p> <p>ALL other plans:</p> <ul style="list-style-type: none"> <li>• Allogenic blood transfusion in a surgery patient <ul style="list-style-type: none"> <li>○ BCBSNM: 3 months</li> <li>○ 1 month for all other plans</li> </ul> </li> <li>• Anemia due to myelosuppressive chemotherapy for a non-myeloid malignancy: 6 months</li> <li>• Anemia associated with chronic kidney disease in patients on/not on dialysis, anemia due to myelodysplastic syndrome, anemia resulting from zidovudine treatment of HIV infection: 12 months</li> <li>• All other diagnoses: 6 months</li> </ul> <p><b>The requested agent will also be approved when ONE of the following is met:</b></p> <ol style="list-style-type: none"> <li>1. The request is for a BCBS MT Fully Insured or MT HIM member <b>AND</b> <ol style="list-style-type: none"> <li>A. The patient is under the age of 18 years old <b>AND</b></li> <li>B. The patient does NOT have any FDA labeled contraindications to the requested agent <b>AND</b></li> <li>C. The patient has an indication that is supported in TWO articles from major peer-reviewed professional medical journals [e.g., Journal of American Medical Association (JAMA), New England Journal of Medicine (NEJM), Lancet] as generally safe and effective. Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required] <b>AND</b></li> <li>D. There is support for an age in the patient's given age bracket in TWO articles from major peer-reviewed professional medical journals as generally safe and effective. The age brackets are: 1. infancy (birth up to, but not including, 2 years of age), 2. childhood (2 years of age through 11 years of age), 3. adolescence (12 years of age through 17 years of age). Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required] <b>OR</b></li> </ol> </li> <li>2. The request is for a BCBS NM Fully Insured or NM HIM member and ALL of the following: <ol style="list-style-type: none"> <li>A. The patient does NOT have any FDA labeled contraindications to the requested agent <b>AND</b></li> <li>B. The requested indication is a rare disease <b>AND</b></li> <li>C. ONE of the following: <ol style="list-style-type: none"> <li>1. The patient has another FDA labeled indication for the requested agent and route of administration <b>OR</b></li> <li>2. The patient has another indication that is supported in compendia for the requested agent and route of administration <b>OR</b></li> </ol> </li> </ol> </li> <li>3. ALL of the following: <ol style="list-style-type: none"> <li>A. The member resides in Ohio <b>AND</b></li> </ol> </li> </ol>

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	<p>B. The plan is Fully Insured or HIM Shop (SG) <b>AND</b></p> <p>C. The patient does NOT have any FDA labeled contraindications to the requested agent <b>AND</b></p> <p>D. ONE of the following:</p> <ol style="list-style-type: none"> <li>1. The patient has another FDA labeled indication for the requested agent and route of administration <b>OR</b></li> <li>2. The patient has another indication that is supported in compendia for the requested agent and route of administration <b>OR</b></li> <li>3. The prescriber has submitted TWO articles from major peer-reviewed professional medical journals [e.g., Journal of American Medical Association (JAMA), New England Journal of Medicine (NEJM), Lancet] supporting the proposed use(s) as generally safe and effective. Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required]</li> </ol> <p><b>Non-oncology compendia allowed:</b> DrugDex level 1, 2A or 2B, AHFS-DI (narrative text must be supportive)</p> <p><b>Oncology compendia allowed:</b> NCCN 1 or 2A, AHFS-DI (narrative text must be supportive), DrugDex level 1, 2A, or 2B, or Clinical Pharmacology (narrative text must be supportive), Lexi-Drugs evidence level A, peer-reviewed medical literature</p> <p><b>Length of Approval:</b></p> <p>BCBSOK: 36 months</p> <p>ALL other plans: 12 months</p>

Criteria in this program are consistent with Health Care Service Corporation (HCSC) Medical Policy Rx501.069 Erythropoiesis-Stimulating Agents (ESAs).