curative

Erythropoietins Prior Authorization

Drug(s) Applied:	**Retacrit** (epoetin-alfa)

Criteria:
Drug(s) Applied will be approved when the requested medication is being used for an FDA approved or compendia-supported indication and all of the following criteria are met:

I. Initial Therapy Criteria

A. Anemia in CKD on dialysis as indicated by chart notes within past 120 days

1. Patient's hemoglobin level is < 10g/dL as measured in the past 4 weeks

Approval Duration: 12 months

B. Anemia in CKD not on dialysis as indicated by chart notes within past 120 days

1. ONE of the following:
   a) Patient's hemoglobin level is < 10g/dL as measured in the past 4 weeks **or**
   b) Patient's hemoglobin level is <11 g/dL as measured in the past 4 weeks AND documentation confirms the patient meets at least ONE of the following special clinical circumstances:
      (1) Patient is a pediatric patient (under 18 years of age)
      (2) Patient is an active candidate for a kidney transplant
      (3) Patient has severe, documented physical symptoms directly attributable to anemia (e.g., severe fatigue, dyspnea on exertion) that compromise daily functioning **and**
2. Patient has adequate iron stores as demonstrated by ONE of the following:
   a) Patient's serum ferritin level is ≥100 ng/mL and transferrin saturation is ≥ 20%, as measured within the past 3 months **or**
   b) Patient is receiving supplemental iron therapy **or**
   c) Provider attestation that patient has adequate iron stores **and**
3. Chart notes and/or prescriber do not provide documentation of any FDA labeled contraindications to the requested drug, including but not limited to uncontrolled hypertension **and**
4. Chart notes do not indicate evidence of other causes of anemia (ex: hemolysis, bleeding, vitamin B12 deficiency) **and**
5. The rate of hemoglobin decline is likely to result in a red blood cell (RBC) transfusion **and**

6. Requested agent is being used to reduce the risk of alloimmunization and/or other RBC transfusion related risks

Approval Duration: 12 months

C. Anemia due to myelosuppressive chemotherapy as indicated by chart notes within past 120 days

1. Patient's hemoglobin level is < 10g/dL as measured in the past 4 weeks **and**
2. Patient has adequate iron stores as demonstrated by ONE of the following:
   a) Patient's serum ferritin level is ≥100 ng/mL and transferrin saturation is ≥ 20%, as measured within the past 3 months **or**
   b) Patient is receiving supplemental iron therapy **or**
   c) Provider attestation that patient has adequate iron stores **and**
3. Chart notes and/or prescriber do not provide documentation of any FDA labeled contraindications to the requested drug, including but not limited to uncontrolled hypertension **and**
4. Chart notes do not indicate evidence of other causes of anemia (ex: hemolysis, bleeding, vitamin B12 deficiency) **and**
5. Patient is currently receiving myelosuppressive chemotherapy **and**
6. Patient is concurrently treated with chemotherapy with an anticipated duration of myelosuppressive chemotherapy of ≥2 months **and**
7. Chemotherapy is being used for palliative intent **and**

Approval Duration: 6 months

D. Anemia due to myelodysplastic syndrome or myelofibrosis as indicated by chart notes within past 120 days

1. Patient's hemoglobin level is < 10 g/dL as measured in the past 4 weeks **and**
2. Patient has a serum erythropoietin level ≤ 500 mUnits/mL **and**
3. Patient has adequate iron stores as demonstrated by ONE of the following:
   a) Patient's serum ferritin level is ≥100 ng/mL and transferrin saturation is ≥ 20%, as measured within the past 3 months **or**
   b) Patient is receiving supplemental iron therapy **or**
   c) Provider attestation that patient has adequate iron stores **and**
4. Chart notes and/or prescriber do not provide documentation of any FDA labeled contraindications to the requested drug, including but not limited to uncontrolled hypertension **and**
5. Chart notes do not indicate evidence of other causes of anemia (ex: hemolysis, bleeding, vitamin B12 deficiency) **and**
6. Patient must have a diagnosis of symptomatic anemia (e.g., fatigue, weakness,

malaise, shortness of breath, lightheadedness, pallor, cold extremities, etc.) associated with myelodysplastic syndrome or myelofibrosis

Approval Duration: 12 months

E. Anemia due to HIV treatment with zidovudine as indicated by chart notes within past 120 days

1. Patient's hemoglobin level is < 10g/dL as measured in the past 4 weeks **and**
2. Patient has a serum erythropoietin level ≤ 500 mUnits/mL **and**
3. Patient has adequate iron stores as demonstrated by ONE of the following:
    a) Patient's serum ferritin level is ≥100 ng/mL and transferrin saturation is ≥ 20%, as measured within the past 3 months **or**
    b) Patient is receiving supplemental iron therapy **or**
    c) Provider attestation that patient has adequate iron stores **and**
4. Chart notes and/or prescriber do not provide documentation of any FDA labeled contraindications to the requested drug, including but not limited to uncontrolled hypertension **and**
5. Chart notes do not indicate evidence of other causes of anemia (ex: hemolysis, bleeding, vitamin B12 deficiency) **and**
6. Patient is currently receiving zidovudine therapy at a maximum dose of 4,200 mg/week

Approval Duration: 12 months

F. Reduction of Allogeneic Blood Transfusions in Surgery as indicated by chart notes within past 90 days

1. Patient has perioperative hemoglobin >10g/dL to ≤ 13g/dL as measured in the past 4 weeks **and**
2. Patient has adequate iron stores as demonstrated by ONE of the following:
    a) Patient's serum ferritin level is ≥100 ng/mL and transferrin saturation is ≥ 20%, as measured within the past 3 months **or**
    b) Patient is receiving supplemental iron therapy **or**
    c) Provider attestation that patient has adequate iron stores **and**
3. Chart notes and/or prescriber do not provide documentation of any FDA labeled contraindications to the requested drug, including but not limited to uncontrolled hypertension **and**
4. Chart notes do not indicate evidence of other causes of anemia (ex: hemolysis, bleeding, vitamin B12 deficiency) **and**
5. Requested agent is being used to reduce the possibility of allogeneic blood transfusion in a surgery **and**
6. Surgery is elective, non-cardiac, and non-vascular **and**

7. Patient is unwilling or otherwise unable to participate in an autologous blood donation program prior to surgery

Approval Duration: 1 month

II. Continued Therapy Criteria

A. Anemia in CKD on dialysis as indicated by chart notes within past 12 months

1. Patient's hemoglobin level ≤ 11.5 g/dL as measured in the past 4 weeks

Approval Duration: 12 months

B. Anemia in CKD not on dialysis as indicated by chart notes within past 12 months

1. Patient's hemoglobin level ≤ 11.5 g/dL as measured in the past 4 weeks **and**
2. Patient has adequate iron stores as demonstrated by ONE of the following:
   a) Patient's serum ferritin level is ≥100 ng/mL and transferrin saturation is ≥ 20%, as measured within the past 3 months **or**
   b) Patient is receiving supplemental iron therapy **or**
   c) Provider attestation that patient has adequate iron stores **and**
3. Chart notes and/or prescriber do not provide documentation of any FDA labeled contraindications to the requested drug, including but not limited to uncontrolled hypertension **and**
4. Chart notes do not indicate evidence of other causes of anemia (ex: hemolysis, bleeding, vitamin B12 deficiency)

Approval Duration: 12 months

C. Anemia due to myelosuppressive chemotherapy as indicated by chart notes within past 6 months

1. Patient's hemoglobin level is ≤ 12g/dL as measured in the past 4 weeks **and**
2. Patient has adequate iron stores as demonstrated by ONE of the following:
   a) Patient's serum ferritin level is ≥100 ng/mL and transferrin saturation is ≥ 20%, as measured within the past 3 months **or**
   b) Patient is receiving supplemental iron therapy **or**
   c) Provider attestation that patient has adequate iron stores **and**
3. Chart notes and/or prescriber do not provide documentation of any FDA labeled contraindications to the requested drug, including but not limited to uncontrolled hypertension **and**
4. Chart notes do not indicate evidence of other causes of anemia (ex: hemolysis, bleeding, vitamin B12 deficiency) **and**
5. Patient is continuing to receive myelosuppressive chemotherapy **and**

6. Patient is concurrently treated with chemotherapy with an anticipated duration of myelosuppressive chemotherapy of ≥2 months **and**
7. Chemotherapy is being used for palliative intent

Approval Duration: 6 months

D. Anemia due to myelodysplastic syndrome or myelofibrosis as indicated by chart notes within past 12 months

1. Patient's hemoglobin level is < 12g/dL as measured in the past 4 weeks **and**
2. Patient has adequate iron stores as demonstrated by ONE of the following:
   a) Patient's serum ferritin level is ≥100 ng/mL and transferrin saturation is ≥ 20%, as measured within the past 3 months **or**
   b) Patient is receiving supplemental iron therapy **or**
   c) Provider attestation that patient has adequate iron stores **and**
3. Chart notes and/or prescriber do not provide documentation of any FDA labeled contraindications to the requested drug, including but not limited to uncontrolled hypertension **and**
4. Chart notes do not indicate evidence of other causes of anemia (ex: hemolysis, bleeding, vitamin B12 deficiency)

Approval Duration: 12 months

E. Anemia due to HIV treatment with zidovudine as indicated by chart notes within past 12 months

1. Patient's hemoglobin level is < 12g/dL as measured in the past 4 weeks **and**
2. Patient has adequate iron stores as demonstrated by ONE of the following:
   a) Patient's serum ferritin level is ≥100 ng/mL and transferrin saturation is ≥ 20%, as measured within the past 3 months **or**
   b) Patient is receiving supplemental iron therapy **or**
   c) Provider attestation that patient has adequate iron stores **and**
3. Chart notes and/or prescriber do not provide documentation of any FDA labeled contraindications to the requested drug, including but not limited to uncontrolled hypertension **and**
4. Chart notes do not indicate evidence of other causes of anemia (ex: hemolysis, bleeding, vitamin B12 deficiency) **and**
5. Patient is currently receiving zidovudine therapy at a maximum dose of 4,200 mg/week

Approval Duration: 12 months

F. Reduction of Allogeneic Blood Transfusions in Surgery as indicated by chart notes

within past 90 days

1. Review under Initial Therapy Criteria

Approval Duration: N/A

References:

1. Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) for Erythropoiesis Stimulating Agents (ESAs) in Cancer and Related Neoplastic Conditions (110.21). Effective April 7, 2008.
2. Kidney Disease: Improving Global Outcomes (KDIGO) Anemia Work Group. KDIGO 2026 Clinical Practice Guideline for the Management of Anemia in Chronic Kidney Disease. Kidney International Supplements. 2026
3. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Myelodysplastic Syndromes. Version 2.2025.
4. Procrit prescribing information. Amgen Inc. Janssen Products, LP. April 2024.
5. Retacrit prescribing information. Pfizer Inc. June 2024.
6. Tibi P, McClure RS, Huang J, et al. STS/SCA/AmSECT/SABM Update to the Clinical Practice Guidelines on Patient Blood Management. The Annals of Thoracic Surgery. 2021;112(3):981-1004.U.S. Food and Drug Administration (FDA). Center for Drug Evaluation and Research (CDER). FDA Drug Safety Communication: Modified dosing recommendations to improve the safe use of Erythropoiesis-Stimulating Agents (ESAs) in chronic kidney disease. Safety announcement issued June 24, 2011.

Policy Owned by: Curative PBM team