curative

Erythropoietins Prior Authorization

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

Curative considers Retacrit to be the preferred erythropoietin stimulating agent. All other medications are considered non-preferred including Procrit and Aranesp.

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 less than 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 serum ferritin is > 100 ng/mL, **or**
   b) serum transferrin saturation (TSAT) > 20 %, **or**
   c) hemoglobin level is less than 10g/dL as measured in the past 4 weeks **and**
2. The rate of hemoglobin decline is likely to result in a red blood cell (RBC) transfusion **and**
3. Requested agent is being used to reduce the risk of alloimmunization and/or other RBC transfusion related risks **and**
4. ONE of the following:
   a) Patient's serum ferritin level is greater than or equal to 100ng/mL and patient's transferrin saturation is greater than or equal to 20%, both as measured in the past 4 weeks **or**
   b) Patient has started supplemental iron therapy **and**
5. 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

Approval Duration: 12 months

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

past 120 days

1. Patient is receiving myelosuppressive chemotherapy **and**
2. Patient's hemoglobin level is less than 10g/dL or the hematocrit is < 30% as measured in the past 4 weeks **and**
3. Patient is concurrently treated with chemotherapy with an anticipated duration of myelosuppressive chemotherapy of ≥2 months **and**
4. Chemotherapy is being used for palliative intent **and**
5. Patient does not have evidence of other causes of anemia (e.g., iron deficiency, hemolysis, bleeding, folate deficiency, vitamin B12 deficiency, bone marrow fibrosis) **and**
6. ONE of the following:
    a) Patient's serum ferritin level is greater than 100ng/mL **or**
    b) serum transferrin saturation (TSAT) > 20 %, **or**
    c) Patient is receiving supplemental iron therapy and patient's hemoglobin is <10 g/dL, **and**
7. 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

Approval Duration: 6 months

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

1. 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 **and**
2. Patient's hemoglobin level is less than 12g/dL as measured in the past 4 weeks **and**
3. ONE of the following:
    a) Patient's serum ferritin level is greater than or equal to 100ng/mL and patient's transferrin saturation is greater than or equal to 20%, both as measured in the past 4 weeks **or**
    b) Patient has started supplemental iron therapy **and**
4. Patient's age is within FDA labeling for the requested indication or there is support for using the requested agent for the patient's age for the requested indication **and**
5. Patient must have a serum erythropoietin level ≤ 500 mUnits/mL **and**
6. Patient does not have evidence of other causes of anemia (e.g., iron deficiency, hemolysis, bleeding, folate deficiency, vitamin B12 deficiency) **and**
7. 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

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 less than 12g/dL as measured in the past 4 weeks **and**
2. ONE of the following:
    a) Patient's serum ferritin level is greater than or equal to 100ng/mL and patient's transferrin saturation is greater than or equal to 20%, both as measured in the past 4 weeks **or**
    b) Patient has started supplemental iron therapy **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

Approval Duration: 12 months

F. Surgery as indicated by chart notes within past 90 days

1. Requested agent is being used to reduce the possibility of allogeneic blood transfusion in a surgery **and**
2. Patient has perioperative hemoglobin >10g/dL to ≤ 13g/dL as measured in the past 4 weeks **and**
3. ONE of the following:
    a) Patient's serum ferritin level is greater than or equal to 100ng/mL and patient's transferrin saturation is greater than or equal to 20%, both as measured in the past 4 weeks **or**
    b) Patient has started supplemental iron therapy **and**
4. Patient's age is within FDA labeling for the requested indication or there is support for using the requested agent for the patient's age for the requested indication **and**
5. 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

Approval Duration: 1 month

G. Other compendia-supported indication as indicated by chart notes within past 120 days

1. ONE of the following:
    a) Patient's indication is oncology-related or myelofibrosis-related and supported by NCCN (category 2A or above) **or**
    b) Red blood cell transfusion refusal with documented religious reason for refusal (e.g., Jehovah's witness) **and**
2. Patient's hemoglobin level is within compendia-supported range as measured in the past 4 weeks **and**
3. ONE of the following:
    a) Patient's serum ferritin level is greater than or equal to 100ng/mL and patient's transferrin saturation is greater than or equal to 20%, both as measured in the past 4 weeks **or**
    b) Patient has started supplemental iron therapy **and**
4. Patient's age is within FDA labeling for the requested indication or there is support for using the requested agent for the patient's age for the requested indication **and**
5. 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

Approval Duration: 6 months

II. Continued Therapy Criteria

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

1. Patient's hemoglobin level is less than 11g/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 is less than 11g/dL as measured in the past 4 weeks **and**
2. ONE of the following:
    a) Patient's serum ferritin level is greater than or equal to 100ng/mL and patient's transferrin saturation is greater than or equal to 20%, both as measured in the past 4 weeks **or**
    b) Patient is currently receiving supplemental iron therapy
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

Approval Duration: 12 months

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

past 6 months

1. Patient is continuing to receive myelosuppressive chemotherapy for a non-myeloid, non-erythroid malignancy **and**
2. Patient's hemoglobin level is less than 12g/dL as measured in the past 4 weeks **and**
3. Patient is concurrently treated with chemotherapy with an anticipated duration of myelosuppressive chemotherapy of ≥2 months **and**
4. Chemotherapy is being used for palliative intent **and**
5. Patient does not have evidence of other causes of anemia (e.g., iron deficiency, hemolysis, bleeding, folate deficiency, vitamin B12 deficiency, bone marrow fibrosis) **and**
6. Patient's serum ferritin level is NOT greater than 800ng/mL as measured in the past 4 weeks **and**
7. Patient's transferrin saturation is NOT greater than 50% as measured in the past 4 weeks **and**
8. ONE of the following:
    a) Patient's serum ferritin level is greater than or equal to 100ng/mL and patient's transferrin saturation is greater than or equal to 20%, both as measured in the past 4 weeks **or**
    b) Patient has started supplemental iron therapy **and**
9. Patient is at least 5 years old **and**
10. 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

Approval Duration: 6 months

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

1. Patient's hemoglobin level is less than 12g/dL as measured in the past 4 weeks **and**
2. ONE of the following:
    a) Patient's serum ferritin level is greater than or equal to 100ng/mL and patient's transferrin saturation is greater than or equal to 20%, both as measured in the past 4 weeks **or**
    b) Patient has started supplemental iron therapy **and**
3. Patient's age is within FDA labeling for the requested indication or there is support for using the requested agent for the patient's age for the requested indication **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

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 less than 12g/dL as measured in the past 4 weeks **and**
2. ONE of the following:
    a) Patient's serum ferritin level is greater than or equal to 100ng/mL and patient's transferrin saturation is greater than or equal to 20%, both as measured in the past 4 weeks **or**
    b) Patient has started supplemental iron therapy **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

Approval Duration: 12 months

F. Surgery as indicated by chart notes within past 90 days

1. Review under Initial Therapy Criteria

Approval Duration: N/A

G. Other compendia-supported indication as indicated by chart notes within past 6 months

1. ONE of the following:
    a) Patient's indication is oncology-related or myelofibrosis-related and supported by NCCN (category 2A or above) **or**
    b) Red blood cell transfusion refusal with documented religious reason for refusal (e.g., Jehovah's witness) **and**
2. Patient's hemoglobin level is within compendia-supported range as measured in the past 4 weeks **and**
3. ONE of the following:
    a) Patient's serum ferritin level is greater than or equal to 100ng/mL and patient's transferrin saturation is greater than or equal to 20%, both as measured in the past 4 weeks **or**
    b) Patient has started supplemental iron therapy **and**
4. Patient's age is within FDA labeling for the requested indication or there is support for using the requested agent for the patient's age for the requested indication **and**

5. 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

Approval Duration: 6 months

If submitting for medical billing:

Q5106, epoetin alfa-epbx (Retacrit) non-ESRD, 1 unit = 1000 dosing units

Q5105, epoetin alfa-epbx (Retacrit) ESRD, 1 unit = 100 dosing units