1. **Anemia in a Patient with Chronic Kidney Disease who is on Dialysis.** Approve for 3 years.

2. **Anemia in a Patient with Chronic Kidney Disease who is not on Dialysis.** Approve for 1 year if the patient meets the following criteria (A or B):
   - **A)** Initial Therapy. Approve if the patient meets the following criteria (i and ii):
     - **i.** Patient meets one of the following (a or b):
       - **a)** Patient is ≥ 18 years of age with a hemoglobin < 10.0 g/dL; OR
       - **b)** Patient is < 18 years of age with a hemoglobin ≤ 11.0 g/dL; AND
     - **ii.** Patient meets one of the following (a or b):
       - **a)** Patient is currently receiving iron therapy; OR
       - **b)** Patient has adequate iron stores according to the prescriber; OR
   - **B)** Patient is Currently Receiving an Erythropoiesis-Stimulating Agent. Approve if the patient meets the following criteria (i and ii):
     Note: Examples of erythropoiesis-stimulating agents include an epoetin alfa product (e.g., Epogen, Procrit, or Retacrit), a darbepoetin alfa product (e.g., Aranesp), or a methoxy polyethylene glycol-epoetin beta product (e.g., Mircera).
     - **i.** Patient has a hemoglobin ≤ 12.0 g/dL; AND
     - **ii.** Patient meets one of the following (a or b):
       - **a)** Patient is currently receiving iron therapy; OR
       - **b)** Patient has adequate iron stores according to the prescriber.

3. **Anemia in a Patient with Cancer due to Cancer Chemotherapy.** Approve for 6 months if the patient meets the following criteria (A or B):
   - **A)** Initial Therapy. Approve if the patient meets the following criteria (i, ii, and iii):
     - **i.** Patient has a hemoglobin < 10.0 g/dL; AND
     - **ii.** Patient meets BOTH of the following (a and b):
       - **a)** Patient is currently receiving myelosuppressive chemotherapy; AND
       - **b)** According to the prescriber, myelosuppressive chemotherapy is considered non-curative; AND
     - **iii.** Patient meets one of the following (a or b):
       - **a)** Patient is currently receiving iron therapy; OR
       - **b)** Patient has adequate iron stores according to the prescriber; OR
   - **B)** Patient is Currently Receiving an Erythropoiesis-Stimulating Agent. Approve if the patient meets the following criteria (i, ii, and iii):
     Note: Examples of erythropoiesis-stimulating agents include an epoetin alfa product (e.g., Epogen, Procrit, or Retacrit) or a darbepoetin alfa product (e.g., Aranesp).
     - **i.** Patient has a hemoglobin ≤ 12.0 g/dL; AND
     - **ii.** Patient meets BOTH of the following (a and b):
       - **a)** Patient is currently receiving myelosuppressive chemotherapy; AND
       - **b)** According to the prescriber, myelosuppressive chemotherapy is considered non-curative; AND
     - **iii.** Patient meets one of the following (a or b):
       - **a)** Patient is currently receiving iron therapy; OR
       - **b)** Patient has adequate iron stores according to the prescriber.

4. **Anemia in a Patient with Human Immunodeficiency Virus who is Receiving Zidovudine.** Approve for 1 year if the patient meets the following criteria (A or B):
   - **A)** Initial Therapy. Approve if the patient meets the following criteria (i, ii, and iii):
     - **i.** Patient meets one of the following (a or b):
       - **a)** Patient has a hemoglobin < 10.0 g/dL; OR

b) Patient has a serum erythropoietin level ≤ 500 mU/mL; AND
ii. Patient is currently receiving zidovudine therapy; AND
iii. Patient meets one of the following (a or b):
a) Patient is currently receiving iron therapy; OR
b) Patient has adequate iron stores according to the prescriber; OR

B) Patient is Currently Receiving an Erythropoiesis-Stimulating Agent. Approve if the patient meets the following criteria (i, ii, and iii):
Note: Examples of erythropoiesis-stimulating agents include an epoetin alfa product (e.g., Epogen, Procrit, or Retacrit) or darbepoetin alfa product (e.g., Aranesp).
i. Patient has a hemoglobin ≤ 12.0 g/dL; AND
ii. Patient is currently receiving zidovudine therapy; AND
iii. Patient meets one of the following (a or b):
a) Patient is currently receiving iron therapy; OR
b) Patient has adequate iron stores according to the prescriber.

5. **Reduction of Allogeneic Red Blood Cell Transfusions in a Patient Undergoing Surgery.** Approve for 1 month if the patient meets the following criteria (A, B, C, and D):
A) Hemoglobin is ≤ 13.0 g/dL; AND
B) The surgery is elective, nonvascular, and noncardiac; AND
C) Patient is not willing or able to donate autologous blood prior to surgery; AND
D) Patient meets one of the following (i or ii):
i. Patient is currently receiving iron therapy; OR
ii. Patient has adequate iron stores according to the prescriber.

Other Uses with Supportive Evidence

6. **Anemia Associated with Myelodysplastic Syndrome.** Approve for 1 year if the patient meets the following criteria (A or B):
A) Initial Therapy. Approve if the patient meets the following criteria (i, ii, iii, and iv):
i. Patient is ≥ 18 years of age; AND
ii. Patient meets one of the following (a or b):
a) Patient has a hemoglobin < 10.0 g/dL; OR
b) Patient has a serum erythropoietin level ≤ 500 mU/mL; AND
iii. Patient meets one of the following (a or b):
a) Patient is currently receiving iron therapy; OR
b) Patient has adequate iron stores according to the prescriber; AND
iv. The medication is prescribed by or in consultation with a hematologist or oncologist.
B) Patient is Currently Receiving an Erythropoiesis-Stimulating Agent. Approve if the patient meets the following criteria (i, ii, iii, and iv):
Note: Examples of erythropoiesis-stimulating agents include an epoetin alfa product (e.g., Epogen, Procrit, or Retacrit) or a darbepoetin alfa product (e.g., Aranesp).
i. Patient is ≥ 18 years of age; AND
ii. Patient has a hemoglobin ≤ 12.0 g/dL; AND
iii. Patient meets one of the following (a or b):
a) Patient is currently receiving iron therapy; OR
b) Patient has adequate iron stores according to the prescriber; AND
iv. The medication is prescribed by or in consultation with a hematologist or oncologist.

7. **Anemia Associated with Myelofibrosis.** Approve for the duration noted below if the patient meets the following criteria (A or B):
A) Initial Therapy. Approve for 3 months if the patient meets the following criteria (i, ii, and iii):

i. Patient meets one of the following (a or b):
  a) Patient has a hemoglobin < 10.0 g/dL; OR
  b) Patient has a serum erythropoietin level ≤ 500 mU/mL; AND
ii. Patient meets one of the following (a or b):
  a) Patient is currently receiving iron therapy; OR
  b) Patient has adequate iron stores according to the prescriber; AND
iii. The medication is prescribed by or in consultation with a hematologist or oncologist.

B) Patient is Currently Receiving an Erythropoiesis-Stimulating Agent. Approve for 1 year if the patient meets the following criteria (i, ii, iii, and iv):
Note: Examples of erythropoiesis-stimulating agents include an epoetin alfa product (e.g., Epogen, Procrit, or Retacrit) or a darbepoetin alfa product (e.g., Aranesp).
i. Patient has a hemoglobin ≤ 12.0 g/dL; AND
ii. Patient meets one of the following (a or b):
  a) Patient is currently receiving iron therapy; OR
  b) Patient has adequate iron stores according to the prescriber; AND
iii. According to the prescriber, patient has responded to therapy defined as hemoglobin ≥ 10 g/dL or a hemoglobin increase of ≥ 2 g/dL; AND
iv. The medication is prescribed by or in consultation with a hematologist or oncologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Epoetin alfa is not recommended in the following situations:

1. **Anemia Associated with Cancer in a Patient not Receiving Myelosuppressive Cancer Chemotherapy.** Epoetin alfa is not indicated in patients with cancer who are not receiving cancer chemotherapy.[1-3]

2. **Anemia Associated with Acute Myelogenous Leukemias (AML), Chronic Myelogenous Leukemias (CML) or other Myeloid Cancers.** Epoetin alfa is indicated for use in non-myeloid cancers. AML and CML are examples of myeloid cancers.[1-3]

3. **Anemia Associated with Radiotherapy in Cancer.** Epoetin alfa is not indicated for use in patients with cancer who are given only radiation therapy.[1-3]

4. **To Enhance Athletic Performance.** Epoetin alfa is not recommended for approval because this indication is excluded from coverage in a typical pharmacy benefit.

5. **Anemia due to Acute Blood Loss.** Use of Epoetin alfa is not appropriate in these types of situations.

6. **Non-Anemic Patients (Hemoglobin > 13.0 g/dL) Prior to Surgery.** Although studies have been done that involved non-anemic patients undergoing various surgeries receiving epoetin alfa preoperatively and sometimes postoperatively to prevent transfusions or subsequent anemia, the overall benefit of this therapy in those with relatively normal preoperative Hb level is questionable.

7. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

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3. Retacrit® subcutaneous or intravenous injection [prescribing information]. New York, NY and Lake Forest, IL: Pfizer and Hospira; June 2021.
4. Kidney Disease: Improving Global Outcomes (KDIGO) Anemia Work Group. KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease. *Kidney Int*. 2012; 2(Suppl):279-335.
5. The NCCN Myelodysplastic Syndromes Clinical Practice Guidelines in Oncology (version 3.2022 – January 13, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 24, 2022.
6. The NCCN Myeloproliferative Neoplasms Clinical Practice Guidelines in Oncology (version 2.2022 – April 13, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 24, 2022.