total iron-binding capacity, transferrin saturation, or ferritin levels) and instituting iron replacement when needed may be useful in limiting the need for ESAs, maximizing symptomatic improvement in patients, and determining the reason for inadequate response to ESAs. Iron deficiency can occur following continued ESA use. Therefore, iron supplementation is required in most patients to maintain an optimal response.

Aranesp is recommended in several guidelines from the National Comprehensive Cancer Network (NCCN):

- **Myelodysplastic Syndrome (MDS):** NCCN guidelines (version 3.2022 – January 13, 2022) list Aranesp and epoetin alfa products as having utility in anemic, symptomatic patients with MDS if serum erythropoietin levels are ≤ 500 mU/mL.[3] Iron stores should be adequate. Due to safety issues, the guidelines suggest that ESAs be used in the management of symptomatic anemia in patients with MDS and to aim for a target Hb ≤ 12.0 g/dL.
- **Myeloproliferative Neoplasms:** The NCCN guidelines (version 2.2022 – April 13, 2022) address Aranesp and epoetin alfa products as options for treatment of patients with anemia related to myelofibrosis having a serum erythropoietin level ≤ 500 mU/mL.[4] Iron stores should be adequate. The guidelines also advise that ESAs are not effective for the management of transfusion-dependent anemia.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Aranesp in patients with conditions other than CKD who are on dialysis. The intent of this policy is to provide recommendations for uses other than anemia in patients with CKD who are on dialysis. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Aranesp as well as the monitoring required for adverse events and long-term efficacy, approval requires Aranesp to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Aranesp is recommended in those who meet one of the following criteria:

FDA-Approved Indications

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.

Other Uses with Supportive Evidence

4. 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.

5. 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 Aranesp is not recommended in the following situations:

1. Anemia Associated with Cancer in a Patient not Receiving Myelosuppressive Cancer Chemotherapy. Aranesp is not indicated in patients with cancer who are not receiving cancer chemotherapy.[1]

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

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

4. To Enhance Athletic Performance. Aranesp 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 Aranesp is not appropriate in these types of situations.

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

REFERENCES

1. Aranesp® intravenous or subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; January 2019.
2. 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.
3. 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 July 14, 2022.
4. 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 July 14, 2022.