Reference number(s)
1616-A

Specialty Guideline Management
Aranesp

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Aranesp	darbepoetin alfa

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications[1]

Anemia Due to Chronic Kidney Disease

Treatment of anemia due to chronic kidney disease (CKD), including patients on dialysis and patients not on dialysis.

Anemia Due to Chemotherapy in Patients with Cancer

Treatment of anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy.

Compendial Uses

- Symptomatic anemia in patients with myelodysplastic syndromes (MDS)[2,3,8]
- Anemia in patients who will not/cannot receive blood transfusions[9]

- Myelofibrosis-associated anemia[2,5]
- Cancer patients who are undergoing palliative treatment[2]

All other indications are considered experimental/investigational and not medically necessary.

Coverage Criteria

Note: Requirements regarding pretreatment hemoglobin level exclude values due to a recent transfusion. All members must be assessed for iron deficiency anemia and have adequate iron stores (defined as a serum transferrin saturation [TSAT] level greater than or equal to 20% within the prior 3 months) or are receiving iron therapy before starting Aranesp. Members may not use Aranesp concomitantly with other erythropoiesis-stimulating agents.

Anemia Due to Chronic Kidney Disease (CKD)[1,4]

Authorization of 12 weeks may be granted for treatment of anemia due to chronic kidney disease in members with pretreatment hemoglobin less than 10 grams per deciliter (g/dL).

Anemia Due to Myelosuppressive Chemotherapy[1,2]

Authorization of 12 weeks may be granted for treatment of anemia due to myelosuppressive chemotherapy in members with non-myeloid malignancy and pretreatment hemoglobin less than 10 g/dL.

Anemia in Myelodysplastic Syndrome (MDS)[2,6,7]

Authorization of 12 weeks may be granted for treatment of anemia in myelodysplastic syndrome in members with a pretreatment hemoglobin less than 10 g/dL.

Anemia in Members Who Will Not/Cannot Receive Blood Transfusions[8]

Authorization of 12 weeks may be granted for treatment of anemia in members who will not/cannot receive blood transfusions (e.g., religious beliefs) with pretreatment hemoglobin less than 10 g/dL.

Myelofibrosis-associated Anemia[2,5]

Authorization of 12 weeks may be granted for treatment of myelofibrosis-associated anemia in members who meet both of the following criteria:

- Pretreatment hemoglobin less than 10 g/dL.
- Pretreatment serum erythropoietin (EPO) level less than 500 milliunits per milliliter (mU/mL).

Anemia Due to Cancer[2]

Authorization of 12 weeks may be granted for treatment of anemia due to cancer in members who have cancer and are undergoing palliative treatment.

Continuation Of Therapy

Note: Requirements regarding current hemoglobin level exclude values due to a recent transfusion. All members must be assessed for iron deficiency anemia and have adequate iron stores (defined as a serum transferrin saturation [TSAT] level greater than or equal to 20% within the prior 3 months) or are receiving iron therapy before continuation of treatment with Aranesp. Members may not use Aranesp concomitantly with other erythropoiesis-stimulating agents.

For all indications below: All members (including new members) requesting authorization for continuation of therapy after at least 12 weeks of Aranesp treatment must show a response with a rise in hemoglobin of greater than or equal to 1 g/dL. Members who completed less than 12 weeks of Aranesp treatment and have not yet responded with a rise in hemoglobin of greater than or equal to 1 g/dL may be granted authorization of up to 12 weeks to allow for sufficient time to demonstrate a response.

Anemia due to Chronic Kidney Disease (CKD)[1,4]

Authorization of 12 weeks may be granted for continued treatment of anemia due to chronic kidney disease in members with current hemoglobin less than 12 g/dL.

Anemia Due to Myelosuppressive Chemotherapy[1,2]

Authorization of 12 weeks may be granted for continued treatment of anemia due to myelosuppressive chemotherapy in members with non-myeloid malignancy and current hemoglobin less than 12 g/dL.

Anemia in Myelodysplastic Syndrome (MDS)[2,6,7]

Authorization of 12 weeks may be granted for continued treatment of anemia in myelodysplastic syndrome in members with current hemoglobin less than 12 g/dL.

Anemia in members who will not/cannot receive blood transfusions[8]

Authorization of 12 weeks may be granted for continued treatment of anemia in members who will not/cannot receive blood transfusions (e.g., religious beliefs) with current hemoglobin less than 12 g/dL.

Myelofibrosis-associated Anemia[2,5]

Authorization of 12 weeks may be granted for continued treatment of myelofibrosis-associated anemia in members with current hemoglobin less than 12 g/dL.

Anemia Due to Cancer[2]

Authorization of 12 weeks may be granted for continued treatment of anemia due to cancer in members who have cancer and are undergoing palliative treatment.

References

1. Aranesp [package insert]. Thousand Oaks, CA: Amgen Inc.; April 2024.
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3. Micromedex Solutions [database online]. Ann Arbor, MI: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. Accessed September 3, 2024.
4. Kidney Disease: Improving Global Outcomes (KDIGO) Anemia Work Group. KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease. *Kidney Int.* 2012; Suppl 2:279-335.
5. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Myeloproliferative Neoplasms. Version 2.2024. http://www.nccn.org/professionals/physician_gls/pdf/mpn.pdf. Accessed September 3, 2024.
6. Gabrilove J, Paquette R, Lyons R, Mushtaq C, Sekeres M, et al. Phase 2, single-arm trial to evaluate the effectiveness of darbepoetin alfa for correcting anemia in patients with myelodysplastic syndromes. *Br J Haematol.* 2008 Aug; 142(3): 379–393.
7. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Myelodysplastic Syndromes. Version 3.2024. https://www.nccn.org/professionals/physician_gls/pdf/mds.pdf. Accessed September 3, 2024.
8. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Hematopoietic Growth Factors. Version 3.2024. https://www.nccn.org/professionals/physician_gls/pdf/growthfactors.pdf. Accessed September 7, 2024.