

STANDARD MEDICARE PART B MANAGEMENT

ARANESP (darbepoetin)

POLICY

I. 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.

A. FDA-Approved Indications

Treatment of anemia due to:

1. Chronic kidney disease in patients on dialysis and patients not on dialysis
2. The effects of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy

Limitations of Use:

1. Aranesp has not been shown to improve quality of life, fatigue, or patient well-being.
2. Aranesp is not indicated for use:
 - In patients with cancer receiving hormonal agents, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy.
 - In patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure.
 - In patients with cancer receiving myelosuppressive chemotherapy in whom the anemia can be managed by transfusion
 - As a substitute for RBC transfusions in patients who require immediate correction of anemia

Note: Use in members on dialysis is covered under the Medicare Part B dialysis benefit and is excluded from coverage under this policy.

B. Compendial Uses

1. Treatment of anemia due to myelodysplastic syndrome
2. Prophylaxis of anemia of prematurity
3. Anemia in members whose religious beliefs forbid blood transfusions
4. Anemia in myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis
5. Cancer patients who are undergoing palliative treatment

C. Nationally Covered Indication

Centers for Medicare and Medicaid Services guidelines provide coverage for Aranesp for anemia secondary to myelosuppressive chemotherapy based on the criteria in Sections II, III, and IV.

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. EXCLUSIONS

The following exclusions criteria apply to members requesting use for anemia due to concomitant myelosuppressive chemotherapy:

- A. The anemia is due to folate, B-12, or iron deficiency.
- B. The anemia is due to hemolysis, bleeding, or bone marrow fibrosis.
- C. The anemia is due to treatment for acute myelogenous leukemia, chronic myelogenous leukemia, or erythroid cancers.
- D. The anemia is due to treatment with radiotherapy only.
- E. Prophylactic use to prevent chemotherapy-induced anemia
- F. Prophylactic use to reduce tumor hypoxia
- G. Use in members with erythropoietin-type resistance due to neutralizing antibodies
- H. Members with uncontrolled hypertension

III. CRITERIA FOR INITIAL APPROVAL

Note: Requirements regarding current hemoglobin level exclude values due to a recent transfusion.

A. Anemia due to chronic kidney disease

Authorization of 12 weeks may be granted for the treatment of anemia due to chronic kidney disease in members not receiving dialysis with a pretreatment hemoglobin of less than 10 g/dL or a hematocrit of less than 30%.

B. Anemia due to concomitant myelosuppressive chemotherapy

Authorization of 8 weeks may be granted for the treatment of anemia due to concomitant chemotherapy with all of the following criteria are met:

- 1. The member is receiving chemotherapy for a solid tumor, multiple myeloma, lymphoma, or lymphocytic leukemia.
- 2. The hemoglobin level immediately prior to initiation or maintenance of therapy is less than 10 g/dL or the hematocrit is less than 30%.
- 3. The starting dose is not greater than an average of 2.25 mcg/kg per week.

C. Anemia due to myelodysplastic syndrome

Authorization of 12 weeks may be granted for the treatment of anemia due to myelodysplastic syndrome with a pretreatment hemoglobin of less than 10 g/dL or a hematocrit of less than 30%.

D. Prophylaxis of anemia of prematurity

Authorization of 12 weeks may be granted for the prophylaxis of anemia of prematurity in members less than 1 year of age.

E. Anemia in members whose religious beliefs forbid blood transfusions

Authorization of 12 weeks may be granted for members whose religious beliefs forbid blood transfusions whose hemoglobin is less than 10 g/dL or whose hematocrit is less than 30%.

F. Anemia in myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis

Authorization of 12 weeks may be granted for the treatment of anemia due to myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis when all of the following criteria are met:

- 1. The member has a hemoglobin level of less than 10 g/dL or a hematocrit of less than 30%.

- The member has an erythropoietin level of less than 500 mU/mL.

G. Anemia Due to Cancer

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

IV. CONTINUATION OF THERAPY

Note: Requirements regarding current hemoglobin level exclude values due to a recent transfusion.

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

- Authorization of 12 weeks may be granted for treatment of anemia due to concomitant myelosuppressive chemotherapy when all of the following criteria are met:
 - The member is currently receiving therapy with Aranesp.
 - The member does not have any exclusions listed in Section II.
 - The member has experienced at least a 1 g/dL increase in their hemoglobin or a 3% increase in their hematocrit.
 - The member's hemoglobin remains below 11 g/dL or the prescriber will hold or reduce the dose of Aranesp to maintain a hemoglobin level sufficient to avoid transfusion.
 - Treatment will not extend beyond 8 weeks following the final dose of myelosuppressive chemotherapy given in the member's current chemotherapy regimen.
- Authorization of 12 weeks may be granted for all other indications when all of the following criteria are met:
 - The member is currently receiving therapy with Aranesp.
 - The member receiving Aranesp for an indication listed in Section III.
 - Aranesp has been effective for treating the diagnosis or condition.

V. REFERENCES

- Aranesp [package insert]. Thousand Oaks, CA: Amgen Inc.; January 2019.
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- 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.
- National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Hematopoietic Growth Factors. Version 2.2020. http://www.nccn.org/professionals/physician_gls/pdf/growthfactors.pdf. Accessed September 1, 2020.
- National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Myelodysplastic Syndromes. Version 1.2021. http://www.nccn.org/professionals/physician_gls/pdf/mds.pdf. Accessed September 29, 2020.
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- National Coverage Determination (NCD) for Erythropoiesis Stimulating Agents (ESAs) in Cancer and Related Neoplastic Conditions (110.21- Version 1). <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=322&ncdver=1&DocId=110.21&bc=gAAABAAAAAAA%3d%3d&>. Accessed September 1, 2020.