Draft Revised Policy: Do Not Implement

Darbepoetin Alfa (Aranesp®)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

The proposal is to add text/statements in red and to delete text/statements with strikethrough:

POLICY

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

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)
- Anemia in patients who will not/cannot receive ~~whose religious beliefs forbid~~ blood transfusions
- Myelofibrosis-associated anemia ~~Symptomatic anemia in patients with primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis~~
- Cancer patients who are undergoing palliative treatment

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

COVERAGE CRITERIA ~~FOR INITIAL APPROVAL~~

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)
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

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)

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

Anemia in Members Who Will Not/Cannot Receive ~~Whose Religious Beliefs Forbid~~ Blood Transfusions

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

Myelofibrosis-associated Anemia ~~in Primary Myelofibrosis (MF), Post-polycythemia Vera MF, or Post-Essential Thrombocythemia MF~~

Authorization of 12 weeks may be granted for treatment of myelofibrosis-associated anemia in ~~primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis~~ in members who meet both ~~ALL~~ 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

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 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 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 ~~ESA~~ 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 ~~ESA~~ 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)

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

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)

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 ~~whose religious beliefs forbid~~ blood transfusions

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

Myelofibrosis-associated Anemia ~~in Primary Myelofibrosis (MF), Post-polycythemia Vera MF, or Post-Essential Thrombocythemia MF~~

Authorization of 12 weeks may be granted for continued treatment of myelofibrosis-associated anemia ~~in primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis~~ in members with current hemoglobin less than <12 g/dL.

Anemia Due to Cancer

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.

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

1. Aranesp [package insert]. Thousand Oaks, CA: Amgen Inc.; April 2024.
2. National Comprehensive Cancer Network. The NCCN Drugs & Biologics Compendium. http://www.nccn.org. Accessed September 3, 2024.
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.

EFFECTIVE DATE

ID_CHS