

Reference number
1616-A

## SPECIALTY GUIDELINE MANAGEMENT

### ARANESP (darbepoetin alfa)

#### 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

1. Treatment of anemia due to chronic kidney disease (CKD), including patients on dialysis and patients not on dialysis.
2. 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.

##### 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.
  - As a substitute for RBC transfusions in patients who require immediate correction of anemia

##### B. Compendial Uses

1. Symptomatic anemia in patients with myelodysplastic syndromes (MDS)
2. Anemia in patients whose religious beliefs forbid blood transfusions
3. Symptomatic anemia in patients with primary myelofibrosis, post-polycythemia vera myelofibrosis, and post-essential thrombocythemia myelofibrosis

All other indications are considered experimental/investigational and are not a covered benefit.

##### II. CRITERIA FOR INITIAL APPROVAL

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

##### A. **Anemia Due to CKD**

Authorization of 12 weeks may be granted for members with pretreatment hemoglobin < 10 g/dL.

##### B. **Anemia Due to Myelosuppressive Chemotherapy**

Authorization of 12 weeks may be granted for members with nonmyeloid malignancy who meet ALL of the following criteria:

1. The intent of chemotherapy is non-curative
2. Pretreatment hemoglobin < 10 g/dL

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**C. Anemia in MDS**

Authorization of 12 weeks may be granted for members with pretreatment hemoglobin < 10 g/dL.

**D. Anemia in Members Whose Religious Beliefs Forbid Blood Transfusions**

Authorization of 12 weeks may be granted for members with pretreatment hemoglobin < 10 g/dL.

**E. Anemia in Primary Myelofibrosis (MF), Post-polycythemia Vera MF, and Post-Essential Thrombocythemia MF**

Authorization of 12 weeks may be granted for members who meet ALL of the following criteria:

1. Member has symptomatic anemia
2. Pretreatment hemoglobin < 10 g/dL
3. Pretreatment serum erythropoietin level < 500 mU/mL

**III. CONTINUATION OF THERAPY**

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

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

**A. Anemia due to CKD**

Authorization of 12 weeks may be granted for continuation of treatment when the current hemoglobin is  $\leq 12$  g/dL.

**B. Anemia Due to Myelosuppressive Chemotherapy**

Authorization of 12 weeks may be granted for continuation of treatment in members with nonmyeloid malignancy who meet BOTH of the following criteria:

1. The intent of chemotherapy is non-curative
2. Current hemoglobin is < 11 g/dL

**C. Anemia in MDS**

Authorization of 12 weeks may be granted for continuation of treatment when the current hemoglobin is  $\leq 12$  g/dL.

**D. Anemia in members whose religious beliefs forbid blood transfusions**

Authorization of 12 weeks may be granted for continuation of treatment when the current hemoglobin is  $\leq 12$  g/dL.

**E. Anemia in Primary Myelofibrosis, Post-polycythemia Vera Myelofibrosis, and Post-Essential Thrombocythemia Myelofibrosis**

Authorization of 12 weeks may be granted for continuation of treatment when the current hemoglobin is  $\leq 12$  g/dL.

**IV. REFERENCES**

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