

## 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.

###### 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
4. Cancer patients who are undergoing palliative treatment

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. All members must be assessed for iron deficiency anemia and have adequate iron stores or are receiving iron therapy before starting Aranesp. Members may not use Aranesp concomitantly with other erythropoiesis stimulating agents.

###### 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 with pretreatment hemoglobin < 10 g/dL.

###### C. **Anemia in MDS**

Authorization of 12 weeks may be granted for members with pretreatment hemoglobin < 10 g/dL whose pretreatment serum EPO level is < 500 MU/ml.

###### 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.

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**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. Pretreatment hemoglobin < 10 g/dL
2. Pretreatment serum erythropoietin level < 500 mU/mL

**F. Anemia Due to Cancer**

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

### III. CONTINUATION OF THERAPY

Note: Requirements regarding pretreatment hemoglobin level exclude values due to a recent transfusion. 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 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 when the current hemoglobin is < 12 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.

**F. Anemia Due to Cancer**

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

### IV. REFERENCES

Aranesp 1616-A SGM P2018a

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