

# 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<sup>1</sup>

##### 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)<sup>2,3,8</sup>
- Anemia in patients who will not/cannot receive blood transfusions<sup>9</sup>

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1616-A

- Myelofibrosis-associated anemia<sup>2,5</sup>
- Cancer patients who are undergoing palliative treatment<sup>2</sup>

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)<sup>1,4</sup>

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<sup>1,2</sup>

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)<sup>2,6,7</sup>

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<sup>8</sup>

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<sup>2,5</sup>

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).

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## Anemia Due to Cancer<sup>2</sup>

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)<sup>1,4</sup>

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<sup>1,2</sup>

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)<sup>2,6,7</sup>

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<sup>8</sup>

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.

Reference number(s)
1616-A

## Myelofibrosis-associated Anemia<sup>2,5</sup>

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<sup>2</sup>

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

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