

# Aranesp® (darbepoetin alfa) injection



When requesting Aranesp® (darbepoetin alfa) injection for non-oncology anemia, the individual requiring treatment must be diagnosed the following FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indications.

## FDA-Approved Non-Oncology Indications

- Anemia associated with chronic kidney disease (CKD) in individuals on dialysis and individuals not on dialysis

## Approved Non-Oncology Off-Label Compendial Uses

None

## Coverage Guidelines

### Anemia associated with chronic kidney disease (CKD)

Initial authorization:

- The pretreatment hemoglobin (Hgb) level is less than 10 g/dL
- Serum ferritin is greater than or equal to 100 mcg/L OR serum transferrin saturation is greater than or equal to 20% OR individual is receiving supplemental iron.
- All other causes of anemia are ruled out or corrected (e.g., vitamin deficiency, metabolic conditions, bleeding, etc.)
- The individual does **not** have any of the following conditions:
  - Uncontrolled hypertension
  - Pure red cell aplasia that begins after treatment with ESA

Reauthorization:

- Serum ferritin is greater than or equal to 100 mcg/L OR serum transferrin saturation is greater than or equal to 20% OR individual is receiving supplemental iron.
- The patient adequately responded to Aranesp therapy (i.e. an increase in hemoglobin of at least 1 g/dL after at least 12 weeks of therapy).
- The current hemoglobin level is less than 12 g/dL
- The individual does **not** have any of the following conditions:
  - Uncontrolled hypertension
  - Pure red cell aplasia that begins after treatment with ESA

**Approval (Initial and reauthorization) is for 6 months**

## Dosing Requirements

- On dialysis: IV, SubQ: Initial: 0.45 mcg/kg once weekly or 0.75 mcg/kg once every 2 weeks
- Not on dialysis: IV, SubQ: Initial: 0.45 mch/kg once every 4 weeks

## References

1. Aranesp® prescribing information. Thousand Oaks, CA: Amgen, Inc.: October 2017. Accessed June 18, 2018.
2. Klasco RK (Ed): DRUGDEX® system. Thomson Micromedex, Greenwood Village, CO. Accessed June 18, 2018.