

## PHARMACY POLICY STATEMENT

### HAP CareSource™ Marketplace

<b>DRUG NAME</b>	<b>Aranesp (darbepoetin alfa)</b>
<b>BENEFIT TYPE</b>	Medical or Pharmacy
<b>STATUS</b>	Prior Authorization Required

Aranesp, approved by the FDA in 2001, is an erythropoiesis-stimulating agent (ESA) indicated for the treatment of anemia due to 1) chronic kidney disease (CKD) in patients on dialysis and patients not on dialysis, or 2) the effects of concomitant myelosuppressive chemotherapy. Aranesp is longer acting than epoetin alfa and can be administered less frequently.

ESAs are the standard of care for treating anemia in CKD (especially in dialysis patients), reducing the need for blood transfusions. Typically, increased hemoglobin levels are not observed earlier than 2 weeks after treatment initiation. A boxed warning states ESAs increase the risk of death, myocardial infarction, stroke, venous thromboembolism, thrombosis of vascular access, and tumor progression or recurrence. The lowest sufficient dose should be used.

Aranesp (darbepoetin alfa) will be considered for coverage when the following criteria are met:

#### Anemia due to Chronic Kidney Disease (CKD)

For **initial** authorization:

1. Medication must be prescribed by or in consultation with a nephrologist; AND
2. Member has a documented diagnosis of anemia due to chronic kidney disease (GFR below 60 mL/min/1.73 m<sup>2</sup>); AND
3. Member's labs show adequate iron stores with both of the following:
  - a) Transferrin saturation is at least 20%
  - b) Ferritin is at least 100 mcg/L; AND
4. Member's labs show hemoglobin ≤10 g/dL within the last 30 days; AND
5. Member does NOT have uncontrolled hypertension.
6. **Dosage allowed/Quantity limit:**  
 Recommended starting dose for adults with CKD on dialysis: 0.45 mcg/kg IV or SQ weekly, or 0.75 mcg/kg IV or SQ every 2 weeks. IV route is recommended for patients on hemodialysis.  
 Recommended starting dose for adults with CKD not on dialysis: 0.45 mcg/kg IV or SQ at 4-week intervals.  
 Recommended starting dose for pediatrics (1 month to less than 18 years) with CKD: 0.45 mcg/kg IV or SQ weekly; members with CKD *not* on dialysis may also be initiated at 0.75 mcg/kg every 2 weeks.

***If all the above requirements are met, the medication will be approved for 6 months.***



For **reauthorization**:

1. Labs must show stabilized or increased hemoglobin level compared to baseline, not to exceed 11.5 g/dL (12 g/dL for pediatrics); AND
2. Red blood cell transfusions are not required or the number of transfusions has decreased compared to baseline; AND
3. Member has adequate iron stores or is on iron therapy; AND
4. Member has not developed pure red cell aplasia (PRCA).

**If all the above requirements are met, the medication will be approved for an additional 12 months.**

### Anemia due to Chemotherapy in Patients with Cancer

Any request for cancer must be submitted through [NantHealth/Eviti](#) portal.

**HAP CareSource considers Aranesp (darbepoetin alfa) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.**

DATE	ACTION/DESCRIPTION
10/04/2018	New policy for Aranesp created. Hemoglobin requirement expanded. Endogenous serum erythropoietin level requirement removed.
09/26/2022	Transferred to new template. Updated all references. Separated anemia due to chemotherapy to a different section. Removed prescribers except nephrology. Clarified baseline hemoglobin levels and changed from within 14 days to within 30 days. Removed supplemental iron as a requirement (still have to meet lab values for adequate levels). Added hypertension as exclusion. Clarified hemoglobin criterion in renewal section and added upper limit. Added adequate iron to renewal criteria. Added not having PRCA to renewal criteria.
03/19/2025	Updated references. Increased renewal duration from 6 months to 12 months. Inserted "1 month" to peds age in dosing info.

References:

1. Aranesp [package insert]. Thousand Oaks, CA: Amgen; 2024.
2. Klinger AS, Foley RN, Goldfarb DS, et al. KDOQI US commentary on the 2012 KDIGO Clinical Practice Guideline for Anemia in CKD. *Am J Kidney Dis*. 2013;62(5):849-859. doi:10.1053/j.ajkd.2013.06.008
3. Palmer SC, Saglimbene V, Craig JC, Navaneethan SD, Strippoli GF. Darbepoetin for the anaemia of chronic kidney disease. *Cochrane Database Syst Rev*. 2014;(3):CD009297. Published 2014 Mar 31. doi:10.1002/14651858.CD009297.pub2
4. Chung EY, Palmer SC, Saglimbene VM, Craig JC, Tonelli M, Strippoli GF. Erythropoiesis-stimulating agents for anaemia in adults with chronic kidney disease: a network meta-analysis. *Cochrane Database Syst Rev*. 2023;2(2):CD010590. Published 2023 Feb 13. doi:10.1002/14651858.CD010590.pub3

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