Clinical Policy: Darbepoetin alfa (Aranesp)
Reference Number: ERX.SPMN.13
Effective Date: 10/16
Last Review Date: 09/16

See Important Reminder at the end of this policy for important regulatory and legal information.

Policy/Criteria
It is the policy of health plans affiliated with Envolve Pharmacy Solutions® that darbepoetin alfa (Aranesp®) is medically necessary when the following criteria are met:

I. Initial Approval Criteria
   A. Anemia Due to Chronic Kidney Disease (must meet all):
      1. Prescribed by or in consultation with a hematologist or nephrologist;
      2. Diagnosis of anemia of chronic kidney disease (CKD) (dialysis and non-dialysis members);
      3. Does not require immediate correction of anemia;
      4. Adequate iron stores as indicated by serum ferritin level ≥ 100 mcg/L or serum transferrin saturation ≥ 20%;
      5. Other causes of anemia (e.g., vitamin deficiency, metabolic or chronic inflammatory conditions, bleeding, etc.) have been corrected or excluded;
      6. Pretreatment hemoglobin level < 10 g/dL.
   
   Approval duration: 12 weeks

   B. Anemia Due to Chemotherapy in Patients with Cancer (must meet all):
      1. Prescribed by or in consultation with a hematologist or oncologist;
      2. Diagnosis of anemia due to chemotherapy;
      3. Member has non-myeloid malignancy;
      4. Is receiving concomitant myelosuppressive chemotherapy;
      5. There is a minimum of two additional months of planned chemotherapy;
      6. Chemotherapy is being given as palliative treatment;
      7. Does not require immediate correction of anemia;
      8. Adequate iron stores as indicated by serum ferritin level ≥ 100 mcg/L or serum transferrin saturation ≥ 20%;
      9. Other causes of anemia (e.g., vitamin deficiency, metabolic or chronic inflammatory conditions, bleeding, etc.) have been corrected or excluded;
      10. Pretreatment hemoglobin < 10 g/dL.
   
   Approval duration: 8 weeks or duration of chemotherapy course (whichever is less)

   C. Anemia Associated with Myelodysplastic Syndrome (must meet all):
      1. Diagnosis of anemia from myelodysplastic syndrome (MDS);
      2. Serum erythropoietin ≤ 500 mU/mL;
      3. Member does not require immediate correction of anemia;  (Continue)
4. Other causes of anemia (e.g., vitamin deficiency, metabolic or chronic inflammatory conditions, bleeding, etc.) have been corrected or excluded;
5. Adequate iron stores as indicated by serum ferritin level ≥ 100 mcg/L or serum transferrin saturation ≥ 20%;
6. Pretreatment hemoglobin < 10 g/dL.

Approval duration: 12 weeks

D. Other diagnoses/indications: Refer to ERX.SPMN.16 - Global Biopharm Policy.

II. Continued Approval
A. Anemia Due to CKD (must meet all):
   1. Currently receiving medication via health plan benefit or member has previously met all initial approval criteria;
   2. Hemoglobin is responsive to erythropoiesis-stimulating agent (ESA) therapy;
   3. Adequate iron stores as indicated by serum ferritin level ≥ 100 mcg/L or serum transferrin saturation ≥ 20% within the last 3 months;
   4. Current hemoglobin level is one of the following:
      a. Adult on dialysis: ≤ 11 g/dL;
      b. Adult not on dialysis: ≤ 10 g/dL;
      c. Pediatrics (< 18 years): ≤ 12 g/dL.

Approval duration: 12 weeks

B. Anemia Due to Chemotherapy in Patients with Cancer (must meet all):
   1. Currently receiving medication via health plan benefit or member has previously met all initial approval criteria;
   2. Continuation of ESA therapy is concurrent with myelosuppressive chemotherapy;
   3. Length of therapy is one of the following:
      a. Has received < 8 weeks of ESA therapy;
      b. Has received ≥ 8 weeks of ESA therapy and both of the following:
         i. Documented evidence of response to therapy as measured by rise in hemoglobin levels > 1 g/dL;
         ii. No red blood cell transfusions are required;
   4. Current hemoglobin < 10 g/dL;
   5. Adequate iron stores as indicated by serum ferritin level ≥ 100 mcg/L or serum transferrin saturation ≥ 20% within the last 3 months.

Approval duration:
   Has received < 8 weeks of ESA therapy: 8 weeks;
   Has received ≥ 8 weeks of ESA therapy: 8 weeks or until completion of chemotherapy course, whichever is less

C. Anemia Associated with MDS (must meet all):
1. Currently receiving medication via health plan benefit or member has previously met all initial approval criteria;
2. Current hemoglobin ≤ 12 g/dL;
3. Adequate iron stores as indicated by serum ferritin level ≥ 100 mcg/L or serum transferrin saturation ≥ 20% within the last 3 months.

Approval duration: 12 weeks

D. Other diagnoses/indications (must meet 1 or 2):
   1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy; or
   2. Refer to ERX.SPMN.16 - Global Biopharm Policy.

Background
Description/Mechanism of Action:
Darbepoetin alfa is an erythropoiesis-stimulant agent (ESA). It stimulates erythropoiesis by the same mechanism as endogenous erythropoietin.

FDA Approved Indications:
Aranesp is an ESA/injection for intravenous or subcutaneous use indicated for the treatment of anemia due to:
- Chronic kidney disease (CKD) in patients on dialysis and patients not on dialysis.
- The effects of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy.

Limitations of Use
- Aranesp has not been shown to improve quality of life, fatigue, or patient well-being.
- 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 red blood cell transfusions in patients who require immediate correction of anemia.
Appendices
Appendix A: Abbreviation Key
CKD: chronic kidney disease
ESA: erythropoiesis-stimulating agent
MDS: myelodysplastic syndromes
PRCA: pure red cell aplasia

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

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<tr>
<th>HCPCS Codes</th>
<th>Description</th>
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<tr>
<td>J0882</td>
<td>Injection, darbepoetin alfa, 1 mcg (for ESRD on dialysis)</td>
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<tr>
<td>J0881</td>
<td>Injection, darbepoetin alfa, 1 mcg (non-ESRD use)</td>
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Reviews, Revisions, and Approvals
Policy split from USS.CP.PHAR.13 Erythropoiesis Stimulating Agents and converted to new template.
Removed all safety criteria and requests for documentation. Added requirement for adequate iron stores and exclusion of all other causes of anemia.
- Anemia due to chemo: added requirement for current Hgb < 10 g/dL per CMS policy.
- Anemia of CKD: added Hgb requirement for pediatric patients and modified criteria to allow for continued therapy after 12 weeks.
- Anemia due to MDS: removed approval for members with Hgb > 12 g/dL.

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References
**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

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