



## MEDICATION POLICY

**Generic Name:** Darbepoetin Alfa

**Therapeutic Class or Brand Name:** Aranesp®

**Applicable Drugs** (if Therapeutic Class): N/A

**Date of Origin:** 2/1/13

**Date Last Reviewed/Revised:** 9/22/16

**GPI Code:** 8240101511

### **Prior Authorization Criteria (may be considered medically necessary when criteria I through V are met):**

- I. Documented diagnosis of one of the following conditions A through B AND must meet criteria listed under applicable diagnosis:
  - A. Anemia due to Chronic Kidney Disease (CKD), including patients on dialysis and patients not on dialysis, and criterion 1 is met:
    1. Minimum age requirement: 1 year old.
  - B. Anemia due to the effects of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy, and criterion 1 is met:
    1. Minimum age requirement: 18 years old.
- II. Prescribing authority limited to hematologist, oncologist, nephrologist, and gastroenterologist or based upon a consult with one of these specialists.
- III. Documentation showing that the patient does not have any GI bleeding.
- IV. Documentation that current hemoglobin is less than 10 g/dL.
- V. Documented failure, intolerance, or contraindication to Procrit®.

### **Exclusion Criteria:**

- Patients with cancer receiving hormonal agents, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy.
- Patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure.
- As a substitute for RBC transfusions in patients who require immediate correction of anemia.
- Patients with uncontrolled hypertension.

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- Patients with Pure Red Cell Aplasia (PRCA) that begins after treatment with erythropoietin protein drugs.

### Other Criteria:

- N/A

### Quantity/Days Supply Restrictions:

- The quantity is limited to a maximum of a 30 day supply per fill.

### Approval Length:

- **Authorization:** 6 months.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing no GI bleeding and hemoglobin less than 11 g/dL.

### Appendix:

N/A

### References:

1. <http://www.fda.gov/Drugs/DrugSafety/ucm259639.htm>.
2. Medi-Span.
3. [http://pi.amgen.com/united\\_states/aranesp/ckd/aranesp\\_pi\\_hcp\\_english.pdf](http://pi.amgen.com/united_states/aranesp/ckd/aranesp_pi_hcp_english.pdf).

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<b>Historical Tracking Of Changes Made To Policy</b>	
9/22/2016	<ol style="list-style-type: none"> <li>1. <b>Changed</b> “III. No GI bleeding” to “III. Documentation showing that the patient does not have any GI bleeding” <b>under Prior Authorization Criteria.</b></li> <li>2. <b>Changed</b> “IV. Hemoglobin less than 10 g/dL” to “IV. Documentation that current hemoglobin is less than 10 g/dL” <b>under Prior Authorization Criteria.</b></li> <li>3. <b>Removed</b> “<a href="https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/Aranesp.pdf">https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/Aranesp.pdf</a>” <b>from References</b> (link no longer valid).</li> </ol>
3/4/2015	<ol style="list-style-type: none"> <li>1. <b>Changed</b> “N/A” to “The quantity is limited to a maximum of a 30 day supply per fill” <b>under Quantity/Days Supply Restrictions.</b></li> <li>2. <b>Updated</b> “<a href="http://www.health.utah.gov/medicaid/pharmacy/priorauthorization/pdf/Aranesp.pdf">http://www.health.utah.gov/medicaid/pharmacy/priorauthorization/pdf/Aranesp.pdf</a>” to “<a href="https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/Aranesp.pdf">https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/Aranesp.pdf</a>” <b>under References.</b></li> </ol>
11/7/2013	<ol style="list-style-type: none"> <li>1. <b>Adapted policy to new format.</b></li> <li>2. <b>Changed Generic Name from</b> “Darbepoetin” to “Darbepoetin Alfa”.</li> <li>3. <b>Added GPI Code.</b></li> <li>4. <b>Added</b> “Documented failure, intolerance, or contraindication to Procrit” <b>requirement.</b></li> <li>5. <b>Changed Re-Authorization from</b> “No GI bleeding and Hemoglobin less than 11 g/dL” <b>to</b> “An updated letter of medical necessity or progress notes showing no GI bleeding and hemoglobin less than 11 g/dL”.</li> <li>6. <b>Updated references</b> to include Medi-Span.</li> </ol>

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