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:** 12/1/17

GPI Code: 8240101510

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.
- Patients with cancer receiving myelosuppressive chemotherapy when the anemia can be managed by transfusion.

- As a substitute for RBC transfusions in patients who require immediate correction of anemia.
- Patients with uncontrolled hypertension.
- 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.

MEDICATION POLICY

Historical Tracking Of Changes Made To Policy	
12/1/2017	1. **Updated** "8240101511" **to** "8240101511" **following GPI Code**. 2. **Added** "Patients with cancer receiving myelosuppressive chemotherapy when the anemia can be managed by transfusion" **under Exclusion Criteria**.
9/22/2016	1. **Changed** "III. No GI bleeding" **to** "III. Documentation showing that the patient does not have any GI bleeding" **under Prior Authorization Criteria**. 2. **Changed** "IV. Hemoglobin less than 10 g/dL" **to** "IV. Documentation that current hemoglobin is less than 10 g/dL" **under Prior Authorization Criteria**. 3. **Removed** "https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/Aranesp.pdf" **from References** (link no longer valid).
3/4/2015	1. **Changed** "N/A" **to** "The quantity is limited to a maximum of a 30 day supply per fill" **under Quantity/Days Supply Restrictions**. 2. **Updated** "http://www.health.utah.gov/medicaid/pharmacy/priorauthorization/pdf/Aranesp.pdf" **to** "https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/Aranesp.pdf" **under References**.
11/7/2013	1. **Adapted policy to new format**. 2. **Changed Generic Name from** "Darbepoetin" **to** "Darbepoetin Alfa". 3. **Added GPI Code**. 4. **Added** "Documented failure, intolerance, or contraindication to Procrit" **requirement**. 5. **Changed Re-Authorization from** "No GI bleeding and Hemoglobin less than 11 g/dL" **to** "An updated letter of medical necessity or progress notes showing no GI bleeding and hemoglobin less than 11 g/dL". 6. **Updated references** to include Medi-Span.