MEDICATION POLICY:

Aranesp®

Generic Name: Darbepoetin Alfa

Therapeutic Class or Brand Name: Aranesp®

Applicable Drugs (if Therapeutic Class): N/A

GPI Code: 8240101510

Preferred: N/A

Non-preferred: N/A

Date of Origin: 2/1/2017

Date Last Reviewed / Revised: 1/8/2020

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.

Historical Tracking of Changes Made to Policy

Date	Notes/ChangesP
1/8/2020	1. Policy reviewed – no changes.
10/12/2018	1. **Added:** registered trademark symbol to reference #2 Medi-Span.
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.

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.