

Generic Name: Epoetin Alfa

Therapeutic Class or Brand Name:
Erythropoietins

Applicable Drugs (if Therapeutic Class):
Epogen[®], Procrit[®], Retacrit[™].

GPI Code: 8240102000, 8240102004.

Preferred: Procrit[®]

Non-preferred: Epogen[®], Retacrit[™]

Date of Origin: 2/1/2013

Date Last Reviewed / Revised: 10/2/2019

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 D AND must meet criteria listed under applicable diagnosis:
 - A. Anemia due to Chronic Kidney Disease in patients on dialysis and patients not on dialysis, and criterion 1 is met:
 1. Minimum age requirement: 1 month old.
 - B. Anemia due to Zidovudine in HIV-infected patients and criterion 1 is met:
 1. Minimum age requirement: 8 months old.
 - C. 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: 5 years old.
 - D. Reduction of allogeneic RBC transfusions in patients undergoing elective, nonvascular, noncardiac surgery and criterion 1 is met (approve one time only):
 1. Minimum age requirement: 18 years old.
- II. Prescribing authority limited to hematologist, oncologist, nephrologist, gastroenterologist, and infectious disease specialist 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. Non-preferred products require a documented failure, intolerance, or contraindication to the preferred product(s). Another item

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.
- Patients scheduled for surgery who are willing to donate autologous blood.
- Patients undergoing cardiac or vascular surgery.
- 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 (unless otherwise stated under Prior Authorization Criteria section).
- **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://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/PROCRI-PI.pdf> .
4. http://pi.amgen.com/united_states/epogen/epogen_pi_hcp_english.pdf.
5. https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/125545s000lbl.pdf .

HISTORICAL TRACKING OF CHANGES MADE TO POLICY

Date	Notes/Changes
10/2/2019	1. Changed obsolete URL item #3 from http://www.procrit.com/sites/all/themes/procrit/resources/ProcritBooklet.pdf to

	<p>http://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/PROCRIT-pi.pdf under References.</p>
10/22/2018	<ol style="list-style-type: none"> 1. Added: Retacrit™ to list of Non-Preferred Products. 2. Added: Reference #5 for Retacrit™ package insert. 3. Added: Registered trademark symbol to reference #2
	<ol style="list-style-type: none"> 1.
12/1/2017	<ol style="list-style-type: none"> 1. Added "Patients with cancer receiving myelosuppressive chemotherapy when the anemia can be managed by transfusion" under Exclusion Criteria.
9/22/2016	<ol style="list-style-type: none"> 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. Changed "V. Non-preferred Epogen® requires a documented failure, intolerance, or contraindication to the preferred product Procrit®" to "V. Non-preferred products require a documented failure, intolerance, or contraindication to the preferred product(s)" under Prior Authorization Criteria. 4. Removed "https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/Erythropoetins.pdf" from References (link no longer valid).
3/4/2015	<ol style="list-style-type: none"> 1. Changed Applicable Drugs from "Procrit® and Epogen®" to "Preferred: Procrit®; Non-Preferred: Epogen®". 2. Deleted duplicate GPI "8240102000". 3. Added "Non-preferred Epogen® requires a documented failure, intolerance, or contraindication to the preferred product Procrit®" under Prior Authorization Criteria. 4. Changed "N/A" to "The quantity is limited to a maximum of a 30 day supply per fill" under Quantity/Days Supply Restrictions. 5. Updated "http://www.health.utah.gov/medicaid/pharmacy/priorauthorization/pdf/Erythropoetins.pdf" to "https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/Erythropoetins.pdf" under References.
11/11/2013	<ol style="list-style-type: none"> 1. Adapted policy to new format. 2. Added GPI Codes. 3. 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". 4. 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.