Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: N/A**
Policy Number: PHW.PDL.038	**Effective Date: 01/01/2020** **Revision Date: 07/2020**
Policy Name: Erythropoiesis Stimulating Proteins	

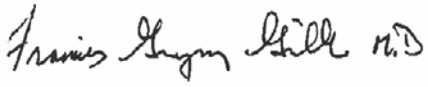
Type of Submission – Check all that apply:

- ☐ **New Policy**
- ☐ **Revised Policy***
- ✓ **Annual Review - No Revisions**
- ✓ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

Q3 2020 annual review: no changes.

Name of Authorized Individual (Please type or print): **Francis G. Grillo, MD**	**Signature of Authorized Individual:** 

Clinical Policy: Erythropoiesis Stimulating Proteins

Reference Number: PHW.PDL.038
Effective Date: 01/01/2020
Last Review Date: 07/2020

Revision Log

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with PA Health and Wellness® that Erythropoiesis Stimulating Proteins is **medically necessary** when the following criteria are met:

I. Requirements for Prior Authorization of Erythropoiesis Stimulating Proteins

A. Prescriptions That Require Prior Authorization

All prescriptions for preferred and non-preferred Erythropoiesis Stimulating Proteins must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for preferred and non-preferred Erythropoiesis Stimulating Proteins, the physician reviewer's determination of whether the requested prescription is medically necessary will take into account the following:

1. For all non-preferred Erythropoiesis Stimulating Proteins, whether the recipient has a documented history of therapeutic failure, contraindication or intolerance of the preferred Erythropoiesis Stimulating Proteins

AND

2. For a diagnosis of anemia associated with chronic kidney disease, whether the recipient:

   a. Has irreversible chronic kidney disease as defined by the National Kidney Foundation's (NKF) Kidney Disease Outcome Quality Initiative (KDOQI)

   AND

   b. Has Hemoglobin < 10 g/dL

   AND

   c. Has transferrin or iron saturation ≥ 20% and ferritin ≥ 100ng/ml

AND

d. Has an evaluation of vitamin B12 and folate levels with therapeutic supplementation as indicated

AND

e. Has adequately controlled blood pressure

AND

f. For pediatrics, is being prescribed the Erythropoiesis Stimulating Protein by, or in consultation with, a specialist in hematology or nephrology

3. **For renewals** of prescriptions for a diagnosis of anemia associated with chronic renal failure, whether the recipient has:

   a. Documented increase in Hemoglobin

   AND

   b. Hemoglobin
      i. ≤ 10 g/dL for recipients not on dialysis
      ii. ≤ 11 g/dL for recipients on dialysis

   AND

   c. Transferrin or iron saturation ≥ 20% and ferritin ≥ 100ng/ml

   AND

   d. Evaluation of vitamin B12 and folate levels with therapeutic supplementation as indicated

   AND

   e. Adequately controlled blood pressure

AND

4. For a diagnosis of anemia in cancer patients on chemotherapy, whether the recipient:

   a. Is currently receiving myelosuppressive chemotherapy

   AND

b. Has Hemoglobin < 10 g/dL

AND

c. Has transferrin or iron saturation ≥ 20% and ferritin ≥ 100ng/ml

AND

d. Has an evaluation of vitamin B12 and folate levels with therapeutic supplementation as indicated

AND

e. Has adequately controlled blood pressure

5. **For renewals** of prescriptions for a diagnosis of anemia in cancer patients on chemotherapy, whether the recipient has:

   a. A documented increase in Hemoglobin

   AND

   b. Hemoglobin ≤ 12 g/dL

   AND

   c. Transferrin or iron saturation ≥ 20% and ferritin ≥ 100ng/ml

   AND

   d. An evaluation of vitamin B12 and folate levels with therapeutic supplementation as indicated

   AND

   e. Adequately controlled blood pressure

AND

6. For a diagnosis of anemia in Zidovudine-treated HIV-infected patients, whether the recipient:

   a. Has a serum erythropoietin level ≤ 500 mUnits/mL

   AND

b. Is receiving a dose of zidovudine ≤ 4200 mg/week

AND

c. Has Hemoglobin < 10 g/dL

AND

d. Has transferrin or iron saturation ≥ 20% and ferritin ≥ 100ng/ml

AND

e. Has an evaluation of vitamin B12 and folate levels with therapeutic supplementation as indicated

AND

f. Has adequately controlled blood pressure

7. **For renewals** of prescriptions for a diagnosis of anemia in Zidovudine-treated HIV-infected patients, whether the recipient has:

a. A documented increase in Hemoglobin

AND

b. Hemoglobin ≤ 12 g/dL

AND

c. Transferrin or iron saturation ≥ 20% and ferritin ≥ 100ng/ml

AND

d. Evaluation of vitamin B12 and folate levels with therapeutic supplementation as indicated

AND

e. Blood pressure is adequately controlled

AND

8. For a reduction of allogeneic blood transfusion in surgery patients, whether the recipient:

a. Has Hemoglobin >10 to ≤ 13 gm/dL

AND

b. Is undergoing elective, noncardiac, nonvascular surgery

AND

c. Has transferrin or iron saturation ≥ 20% and ferritin ≥ 100ng/ml

AND

d. Has an evaluation of vitamin B12 and folate levels with therapeutic supplementation as indicated

AND

e. Has adequately controlled blood pressure

AND

9. For a diagnosis of anemia caused by Ribavirin in patients being treated for hepatitis C, whether the recipient has

   a. Hemoglobin < 10 g/dL or if symptomatic < 11 g/dL

   AND

   b. An evaluation of vitamin B12 and folate levels with therapeutic supplementation as indicated

   AND

   c. Transferrin or iron saturation ≥ 20% and ferritin ≥ 100 ng/mL

   AND

   d. Adequately controlled blood pressure

10. **For renewals** of prescriptions for patients with a diagnosis of Ribavirin-induced anemia, whether the recipient has:

    a. A documented increase in Hemoglobin

    AND

b. Hemoglobin ≤ 12 g/dL

AND

c. An evaluation of vitamin B12 and folate levels with therapeutic supplementation as indicated

AND

d. Transferrin or iron saturation ≥ 20% and ferritin ≥ 100ng/ml

AND

e. Adequately controlled blood pressure

OR

11. The recipient does not meet the clinical review guidelines listed above, but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient.

C. Clinical Review Process

All requests for prior authorization of preferred and non-preferred Erythropoiesis Stimulating Proteins will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when the guidelines in Section B are met or when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient.

D. Approval Duration:

Aranesp	Anemia due to Chronic Kidney Disease	6 months
	Anemia due to Chemotherapy in patients with Cancer:	6 months or until completion of chemotherapy course (whichever is less)
	Anemia associated with Myelodysplastic Syndromes (off-label)	6 months
	Myelofibrosis-Associated Anemia (off-label)	6 months
	Other indications	Duration of request or 6 months (whichever is less)
Epogen, Procrit, Retacrit	Anemia due to Chronic Kidney Disease	6 months
	Anemia due to Zidovudine in HIV-infected patients	6 months

	Anemia due to Chemotherapy in patients with Cancer:	6 months or until completion of chemotherapy course (whichever is less)
	Reduction of Allogeneic Red Blood Cell Transfusions in Patients Undergoing Elective, Noncardiac, Nonvascular Surgery	Duration of request or 6 months (whichever is less)
	Anemia associated with Myelodysplastic Syndromes (off-label)	6 months
	Myelofibrosis-Associated Anemia (off-label)	6 months
	Other indications	Duration of request or 6 months (whichever is less)
Mircera	Anemia due to Chronic Kidney Disease	6 months
	Other indications	Duration of request or 6 months (whichever is less)

E. References

1. CMS Decision Memo for Erythropoiesis Stimulating Agents (ESAs) for non-renal indications (CAG-00383N) URL accessed 11/23/09 at: https://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?from2=viewdecisionmemo.asp&id=203&
2. K/DOQI Clinical Practice Guideline and Clinical Practice Recommendations for Anemia in Chronic Kidney Disease: 2007 Update of Hemoglobin Target. *Am J Kidney Dis* 2007;50(3):471-530.
3. Rizzo JD, Somerfield MR, Hagerty KL, et al. Use of Epoetin and Darbepoetin in Patients With Cancer: 2007 American Society of Clinical Oncology/American Society of Hematology Clinical Practice Guideline Update. J of Clin Oncology 2008;26(1):1-18.
4. Wish JB, Coyne, DW. Use of Erythropoiesis-Stimulating Agents in Patients With Anemia of Chronic Kidney Disease: Overcoming the Pharmacological and Pharmacoeconomic Limitations of Existing Therapies. *Mayo Clin Proc* 2007;81(11):1371-1380.
5. Aranesp prescribing information, Amgen Inc. Thousand Oaks, CA; June 2011
6. Epogen prescribing information Amgen Inc. Thousand Oaks, CA; June 2011
7. Procrit prescribing information Amgen Inc. Thousand Oaks, CA; June 2011
8. Ribavirin prescribing information Roche Laboratories Inc. Nutley, NJ; May 2004
9. Costiniuk et.al. Erythropoiesis-Stimulating Agent Use for Anemia Induced by Interferon-Ribavirin Treatment in Patients with Hepatitis C Virus Infection Is Not Associated with Increased Rates of Cardiovascular Disease, Thrombosis, Malignancy, or Death. Clinical Infectious Disease; 2008:47 (15 July).

Reviews, Revisions, and Approvals	Date
Policy created	01/01/2020

Reviews, Revisions, and Approvals	Date
Q3 2020 annual review: no changes.	07/2020