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: 11/2021**
Policy Number: PHW.PDL.038	**Effective Date: 01/01/2020** **Revision Date: 10/2021**
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:

Q1 2022: policy revised according to DHS revisions effective 01/03/2022

Name of Authorized Individual (Please type or print): **Venkateswara R. Davuluri, MD**	**Signature of Authorized Individual:**

Clinical Policy: Erythropoiesis Stimulating Agents

Reference Number: PHW.PDL.038
Effective Date: 01/01/2020
Last Review Date: 10/2021

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 Erythropoiesis Stimulating Agents must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription an Erythropoiesis Stimulating Agent (ESA) the determination of whether the requested prescription is medically necessary will take into account whether the member:

1. Is prescribed the ESA for the treatment of a diagnosis that is indicate in the U.S. Food and Drug Administration (FDA)-approved package labeling OR medically accepted indication; **AND**

2. Is prescribed the ESA by or in consultation with an appropriate specialist (e.g., gastroenterologist, hematologist/oncologist, infectious disease specialist, nephrologist, surgeon, etc.); **AND**

3. Does not have a contraindication to the prescribed ESA; **AND**

4. Is prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

5. Has been evaluated and treated for other causes of anemia (e.g., iron deficiency, hemolysis, vitamin B12 deficiency, folate deficiency, etc.); **AND**

6. **One** of the following:

   a. Has serum ferritin ≥100mcg/L and serum transferrin saturation ≥20%
   b. Is receiving supplemental iron therapy;

AND

7. For a diagnosis of anemia associated with chronic kidney disease, has pretreatment hemoglobin < 10 g/dL;

AND

8. For a diagnosis of anemia in cancer patients on chemotherapy, **both** of the following:

   a. Has pretreatment hemoglobin < 10g/dL
   b. Is currently receiving myelosuppressive chemotherapy and the anticipated outcome is not cure;

AND

9. For a diagnosis of anemia due to zidovudine in beneficiaries with HIV infection, **all** of the following:

   a. Has pretreatment hemoglobin < 10g/dL,
   b. Has a serum erythropoietin level ≤ 500mUnits/mL,
   c. Is receiving a dose of zidovudine ≤ 4200mg/week;

AND

10. For a reduction of allogeneic blood transfusion in surgery patients, **both** of the following:

    a. Has pretreatment hemoglobin >10 to ≤13 g/dL,
    b. Is undergoing elective, noncardiac, nonvascular surgery;

AND

11. For a non-preferred ESA, has a history of therapeutic failure, contraindication, or intolerance of the preferred ESAs approved or medically accepted for the member's diagnosis.

    NOTE: If the member 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 member, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR ESAs: The determination of medical necessity of a request for renewal of a prior authorization for an ESA that was previously approved will take into account whether the member:

1. **One** of the following:

a. Experienced an increase in hemoglobin compared to baseline
b. Is prescribed an increased dose of the requested ESA consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature;

AND

2. Does not have a contraindication to the prescribed ESA; **AND**

3. Is prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

4. **One** of the following:

   a. Has serum ferritin ≥ 100 mcg/L and serum transferrin saturation ≥ 20%
   b. Is receiving supplemental iron therapy;

   AND

5. For a diagnosis of anemia associated with chronic renal disease, has one of the following:

   a. Hemoglobin ≤ 10 g/dL for beneficiaries not on dialysis
   b. Hemoglobin ≤ 11 g/dL for beneficiaries on dialysis,

   AND

6. For a diagnosis of anemia in cancer patients on chemotherapy, has hemoglobin ≤ 12 g/dL; **AND**

7. For a diagnosis of anemia in zidovudine-treated HIV-infected patients, **all** of the following:

   a. Has hemoglobin ≤ 12 g/dL,
   b. Has a serum erythropoietin level ≤ 500 mUnits/mL,
   c. Is receiving a dose of zidovudine ≤ 4200 mg/week;

   AND

8. For a non-preferred ESA, has a history of therapeutic failure, contraindication, or intolerance of the preferred ESAs approved or medically accepted for the member's diagnosis.

NOTE: If the member 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 member, the request for prior authorization will be approved.

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. Aranesp [package insert]. Thousand Oaks, CA: Amgen Inc. January 2019.
2. Epogen [package insert]. Thousand Oaks, CA: Amgen Inc. July 2018.
3. Mircera [package insert]. St. Gallen, Switzerland: Vifor (International) Inc. June 2018.
4. National Comprehensive Cancer Network. Hematopoietic growth factors (version 4.2021). https://www.nccn.org/professionals/physician_gls/pdf/growthfactors.pdf. Accessed July 7, 2021.
5. Loprinzi CL, Patnaik MM. Role of erythropoiesis-stimulating agents in the treatment of anemia in patients with cancer. Drews RE, Savarese DMF, eds. Waltham, MA: UpToDate Inc. Updated June 30, 2021. Accessed July 7, 2021.
6. KDIGO 2012. KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease, http://www.kdigo.org/clinical_practice_guidelines/pdf/KDIGO-Anemia%20GL.pdf, Accessed 8/17/2021.
7. Klinger AS, Roley RN, Goldfarb DS, et al. KDOQI US Commentary on the 2012 KDIGO Clinical Practice Guidelines fo Anema in CKD. https://www.ajkd.org/article/S0272-6386(13)00978-5/pdf. Accessed 8/17/2021.
8. Bohlius J, Bohlke K, Castelli R, et al. Management of Cancer-Associated Anemia With Erythropoiesis-Stimulating Agents: ASCO/ASH Clinical Practice Guideline Update. J Clin Oncol. 2019 May 20;37(15):1336-1351. doi: 10.1200/JCO.18.02142. Epub 2019 Apr 10. Accessed 8/18/2021.

Reviews, Revisions, and Approvals	Date
Policy created	01/01/2020
Q3 2020 annual review: no changes.	07/2020
Q1 2021 annual review: no changes.	01/2021
Q1 2022: policy revised according to DHS revisions effective 01/03/2022	10/2021