

MEDICAL ASSISTANCE HANDBOOK  
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

**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. See Preferred Drug List (PDL) for the list of preferred Erythropoiesis Stimulating Proteins at:  
[www.providersynergies.com/services/documents/PAM\\_PDL.pdf](http://www.providersynergies.com/services/documents/PAM_PDL.pdf)

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  $\geq 20\%$  and ferritin  $\geq 100\text{ng/ml}$

**AND**

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

**AND**

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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.  $\leq 10$  g/dL for recipients not on dialysis
- ii.  $\leq 11$  g/dL for recipients on dialysis

**AND**

c. Transferrin or iron saturation  $\geq 20\%$  and ferritin  $\geq 100$ ng/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  $\geq 20\%$  and ferritin  $\geq 100$ ng/ml

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**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  $\leq$  12 g/dL

**AND**

c. Transferrin or iron saturation  $\geq$  20% and ferritin  $\geq$  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  $\leq$  500 mUnits/mL

**AND**

b. Is receiving a dose of zidovudine  $\leq$  4200 mg/week

**AND**

c. Has Hemoglobin  $<$  10 g/dL

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**AND**

d. Has transferrin or iron saturation  $\geq 20\%$  and ferritin  $\geq 100\text{ng/ml}$

**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  $\leq 12$  g/dL

**AND**

c. Transferrin or iron saturation  $\geq 20\%$  and ferritin  $\geq 100\text{ng/ml}$

**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  $\leq 13$  gm/dL

**AND**

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b. Is undergoing elective, noncardiac, nonvascular surgery

**AND**

c. Has transferrin or iron saturation  $\geq 20\%$  and ferritin  $\geq 100\text{ng/ml}$

**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  $\geq 20\%$  and ferritin  $\geq 100$  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  $\leq 12$  g/dL

**AND**

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

**AND**

- d. Transferrin or iron saturation  $\geq 20\%$  and ferritin  $\geq 100\text{ng/ml}$

**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.

**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.

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5. Aransep 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).