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

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
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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. $\leq 10 \text{ g/dL}$ for recipients not on dialysis
   ii. $\leq 11 \text{ g/dL}$ for recipients on dialysis

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. 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 $< 10 \text{ g/dL}$

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

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 \( \leq 12 \text{ g/dL} \)

   AND

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

   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 \( \leq 500 \text{ mUnits/mL} \)

   AND

   b. Is receiving a dose of zidovudine \( \leq 4200 \text{ mg/week} \)

   AND

   c. Has Hemoglobin < 10 g/dL
d. Has transferrin or iron saturation $\geq 20\%$ and ferritin $\geq 100$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 $\geq 100$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
b. Is undergoing elective, noncardiac, nonvascular surgery

AND

c. Has transferrin or iron saturation $\geq 20\%$ and ferritin $\geq 100$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
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.

References

5. Aransep prescribing information, Amgen Inc. Thousand Oaks, CA; June 2011


8. Ribavirin prescribing information Roche Laboratories Inc. Nutley, NJ; May 2004