Highmark Wholecare
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

I. Requirements for Prior Authorization of Erythropoiesis Stimulating Agents

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 for an Erythropoiesis Stimulating Agent (ESA), the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the ESA for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a 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 ≥ 100 mcg/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 < 10 g/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 < 10 g/dL,
   b. Has a serum erythropoietin level ≤ 500 mUnits/mL,
   c. Is receiving a dose of zidovudine ≤ 4200 mg/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 beneficiary's diagnosis.

NOTE: If the beneficiary 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 beneficiary, 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 beneficiary:

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 beneficiary's diagnosis.

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

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Erythropoiesis Stimulating Protein. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

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ERYTHROPOIESIS STIMULATING AGENTS PRIOR AUTHORIZATION FORM

☐New request ☐Renewal request	Total # of pgs: _____	Prescriber name:	
Name of office contact:		Specialty:	
Contact's phone number:		NPI:	State license #:
LTC facility contact/phone:		Street address:	
Beneficiary name:		Suite #:	City/State/Zip:
Beneficiary ID#:	DOB:	Phone:	Fax:

CLINICAL INFORMATION

Drug requested:	Strength & vial size:	☐single-dose vial ☐multi-dose vial
Dose/directions:	Quantity:	Duration:
Diagnosis *(submit documentation)*:	Dx code (*required*):	
For non-preferred medication: Does the beneficiary have a history of trial and failure of or contraindication or an intolerance to the preferred agents in this class that are approved or medically accepted for the beneficiary's diagnosis? *Refer to https://papdl.com/preferred-drug-list for a list of preferred and non-preferred drugs in this class.*	☐Yes ☐No	*Submit documentation.*

INITIAL requests

Complete the section(s) below applicable to the beneficiary and this request and SUBMIT DOCUMENTATION for each item.

☐Has transferrin or iron saturation ≥20% and ferritin ≥100 ng/mL
☐Is receiving supplemental iron therapy
☐Has adequately controlled blood pressure
☐Was evaluated and treated for other causes of anemia (e.g., iron deficiency, hemolysis, vitamin B12 deficiency, folate deficiency, etc.)
☐For treatment of anemia associated with CHRONIC KIDNEY DISEASE:
- ☐Has pretreatment hemoglobin <10 g/dL

☐For treatment of anemia in beneficiaries with CANCER RECEIVING CHEMOTHERAPY:
- ☐Is currently receiving myelosuppressive chemotherapy
- ☐Is receiving chemotherapy with a non-curative intent
- ☐At initiation of therapy with an ESA, has an additional 2 or more months of planned chemotherapy
- ☐Has pretreatment hemoglobin <10 g/dL

☐For treatment of anemia in beneficiaries with HIV INFECTION RECEIVING ZIDOVUDINE:
- ☐Has a serum erythropoietin level ≤500 mU/mL ☐Is taking zidovudine at a dose of ≤4200 mg/week
- ☐Has pretreatment hemoglobin <10 g/dL

☐For reduction of ALLOGENEIC BLOOD TRANSFUSIONS in beneficiaries undergoing SURGERY:
- ☐Will be undergoing elective, non-cardiac, non-vascular surgery ☐Is not willing to donate autologous blood pre-operatively
- ☐Is at high risk for perioperative blood loss ☐Has pretreatment hemoglobin >10 g/dL and ≤13 g/dL

RENEWAL requests

Complete the section(s) below applicable to the beneficiary and this request and SUBMIT DOCUMENTATION for each item.

☐Experienced an increase in hemoglobin compared to baseline
☐Is prescribed an increased dose of the requested ESA
☐Has transferrin or iron saturation ≥20% and ferritin ≥100 ng/mL
☐Is receiving supplemental iron therapy
☐Has adequately controlled blood pressure
☐For treatment of anemia associated with CHRONIC KIDNEY DISEASE:
- ☐Is receiving dialysis and has a hemoglobin ≤11 g/dL
- ☐Is not receiving dialysis and has a hemoglobin ≤10 g/dL

☐For treatment of anemia in beneficiaries with CANCER RECEIVING CHEMOTHERAPY:
- ☐Has a hemoglobin ≤12 g/dL

☐For treatment of anemia in beneficiaries with HIV INFECTION RECEIVING ZIDOVUDINE:
- ☐Has a serum erythropoietin level ≤500 mU/mL ☐Is taking zidovudine at a dose of ≤4200 mg/week
- ☐Has a hemoglobin ≤12 g/dL

PLEASE FAX COMPLETED FORM TO HIGHMARK WHOLECARE – PHARMACY DIVISION

Prescriber Signature:	Date: