pennsylvania
DEPARTMENT OF HUMAN SERVICES

MEDICAL ASSISTANCE BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
November 8, 2021	January 3, 2022	*See below

SUBJECT

Prior Authorization of Erythropoiesis Stimulating Agents (ESAs) – Pharmacy Services

BY

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IMPORTANT REMINDER: All providers must revalidate the Medical Assistance (MA) enrollment of each service location every 5 years. Providers should log into PROMISe to check the revalidation dates of each service location and submit revalidation applications at least 60 days prior to the revalidation dates. Enrollment (revalidation) applications may be found at: https://www.dhs.pa.gov/providers/Providers/Pages/PROMISe-Enrollment.aspx.

PURPOSE:

The purpose of this bulletin is to issue updated handbook pages that include the requirements for prior authorization and the type of information needed to evaluate the medical necessity of prescriptions for Erythropoiesis Stimulating Agents (ESAs) submitted for prior authorization.

SCOPE:

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance (MA) Program. The guidelines to determine the medical necessity of ESAs will be utilized in the fee-for-service delivery system and by the MA managed care organizations (MCOs) in Physical Health HealthChoices and Community HealthChoices. Providers rendering services in the MA managed care delivery system should address any questions related to the prior authorization of ESAs to the appropriate MCO.

BACKGROUND:

*01-21-45	09-21-44	27-21-36	33-21-44
02-21-32	11-21-34	30-21-39	
03-21-32	14-21-35	31-21-47	
08-21-47	24-21-42	32-21-32	

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:

The appropriate toll-free number for your provider type.

Visit the Office of Medical Assistance Programs website at https://www.dhs.pa.gov/providers/Providers/Pages/Health%20Care%20for%20Providers/Contact-Information-for-Providers.aspx.

The Department of Human Services' (Department) Pharmacy and Therapeutics (P&T) Committee reviews published peer-reviewed medical literature and recommends the following:

- Preferred or non-preferred status for new drugs in therapeutic classes already included in the Preferred Drug List (PDL);
- Changes in the status of drugs on the PDL from preferred to non-preferred and non-preferred to preferred;
- New quantity limits;
- Classes of drugs to be added to or deleted from the PDL; and
- New guidelines or revisions to existing guidelines to evaluate the medical necessity of prescriptions submitted for prior authorization.

DISCUSSION:

During the September 14, 2021, meeting, the P&T Committee recommended the following revisions to the guidelines to determine medical necessity of ESAs:

- Revision of the Statewide PDL class name from Erythropoiesis Stimulating Proteins to Erythropoiesis Stimulating Agents;
- Addition of a guideline that the requested ESA is prescribed 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;
- Addition of a guideline that the requested ESA be prescribed by or in consultation with an appropriate specialist;
- Addition of a guideline that the beneficiary does not have a contraindication to the prescribed ESA;
- Addition of a guideline that the prescribed dose and duration of therapy are consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature;
- Clarification that the guideline for evaluation and treatment of other causes of anemia applies to requests for the treatment of all diagnoses;
- Clarification that the guideline serum ferritin, serum iron saturation, or supplemental iron therapy applies to requests for the treatment of all diagnoses;
- Clarification that the hemoglobin levels referred to in the guidelines for initial prior authorization requests refer to pretreatment hemoglobin levels;
- Removal of the guideline for a diagnosis of anemia caused by ribavirin in patients being treated for hepatitis C;
- Clarification that the guideline in the requests for renewal of the prior authorization section regarding an increase in hemoglobin applies to all diagnoses;
- Addition of guidelines to the requests for renewal of the prior authorization section that for a diagnosis of anemia in zidovudine-treated HIV-infected patients, the beneficiary has a serum erythropoietin level ≤ 500 mUnits/mL and is receiving a dose of zidovudine ≤ 4200 mg/week; and
- Addition of a guideline to the requests for renewal of the prior authorization section for non-preferred ESAs.

The revisions to the guidelines to determine medical necessity of prescriptions for ESAs submitted for prior authorization, as recommended by the P&T Committee, were subject to public review and comment and subsequently approved for implementation by the Department.

PROCEDURE:

The procedures for prescribers to request prior authorization of ESAs are located in SECTION I of the Prior Authorization of Pharmaceutical Services Handbook. The Department will take into account the elements specified in the clinical review guidelines [which are included in the provider handbook pages in the SECTION II chapter related to Erythropoiesis Stimulating Agents (ESAs)] when reviewing the prior authorization request to determine medical necessity.

As set forth in 55 Pa. Code § 1101.67(a), the procedures described in the handbook pages must be followed to ensure appropriate and timely processing of prior authorization requests for drugs that require prior authorization.

ATTACHMENTS:

Prior Authorization of Pharmaceutical Services Handbook - Updated pages

RESOURCES:

Prior Authorization of Pharmaceutical Services Handbook – SECTION I
Pharmacy Prior Authorization General Requirements
https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Pharmacy-Prior-Authorization-General-Requirements.aspx

Prior Authorization of Pharmaceutical Services Handbook – SECTION II
Pharmacy Prior Authorization Guidelines
https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Clinical-Guidelines.aspx

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.

D. References

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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.