pennsylvania
DEPARTMENT OF HUMAN SERVICES

MEDICAL ASSISTANCE BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
November 16, 2021	January 3, 2022	*See below

SUBJECT

Prior Authorization of Zeposia (ozanimod) – 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 Zeposia (ozanimod) 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 Zeposia (ozanimod) 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 Zeposia (ozanimod) to the appropriate MCO.

BACKGROUND:

*01-21-44	09-21-43	27-21-35	33-21-43
02-21-31	11-21-33	30-21-38	
03-21-31	14-21-34	31-21-46	
08-21-46	24-21-41	32-21-31	

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:

Zeposia (ozanimod) was approved by the U.S. Food and Drug Administration in 2020 for the treatment of multiple sclerosis. The P&T Committee subsequently recommended adding Zeposia (ozanimod) to the Statewide Preferred Drug List (PDL) as non-preferred in the Multiple Sclerosis Agents class. In May 2021, the FDA approved Zeposia (ozanimod) for the treatment of ulcerative colitis.

Recognizing that Zeposia (ozanimod) is now indicated for both multiple sclerosis and ulcerative colitis, the Department of Human Services proposes a requirement for prior authorization and medical necessity guidelines to ensure safe and appropriate utilization of Zeposia (ozanimod) for the treatment of multiple sclerosis and ulcerative colitis.

During the September 15, 2021, P&T Committee meeting, the P&T Committee recommended that the Department require prior authorization of Zeposia (ozanimod) for the treatment of multiple sclerosis and ulcerative colitis to ensure appropriate patient selection and drug utilization. The P&T Committee recommended guidelines to determine medical necessity of Zeposia (ozanimod) that 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 Zeposia (ozanimod) 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 Zeposia (ozanimod)) 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 Zeposia (ozanimod)

A. Prescriptions That Require Prior Authorization

All prescriptions for Zeposia (ozanimod) must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for Zeposia (ozanimod), the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed Zeposia (ozanimod) 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 Zeposia (ozanimod) by or in consultation with an appropriate specialist (i.e., a neurologist for a diagnosis of multiple sclerosis or a gastroenterologist for a diagnosis of ulcerative colitis); **AND**

3. Does not have a contraindication to Zeposia (ozanimod); **AND**

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

5. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

6. For treatment of multiple sclerosis, **one** of the following:

   a. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Multiple Sclerosis Agents approved for the beneficiary's diagnosis
   b. Has a current history (within the past 90 days) of being prescribed Zeposia (ozanimod) (does not apply to non-preferred brands when the therapeutically equivalent generic is preferred or to non-preferred generics when the therapeutically equivalent brand is preferred)

   See the Preferred Drug List (PDL) for the list of preferred Multiple Sclerosis Agents at: https://papdl.com/preferred-drug-list;

   AND

7. For treatment of ulcerative colitis (UC), **both** of the following:

   a. **Both** of the following:

      i. Has **one** of the following diagnoses:

a) Mild UC that is associated with multiple poor prognostic factors[1]
b) Moderate to severe UC

ii. **One** of the following:

a) Failed to achieve remission with or has a contraindication or an intolerance to an induction course of corticosteroids,

b) **One** of the following:

(i) Failed to maintain remission with an immunomodulator in accordance with current consensus guidelines (e.g., American College of Gastroenterology, American Gastroenterological Association, European Crohn's and Colitis Organization, etc.)
(ii) Has a contraindication or an intolerance to immunomodulators in accordance with current consensus guidelines,

c) **Both** of the following:

(i) Has achieved remission with Zeposia (ozanimod)
(ii) Will be using Zeposia (ozanimod) as maintenance therapy to maintain remission

b. **One** of the following:

i. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Cytokine and CAM Antagonists approved or medically accepted for treatment of ulcerative colitis
ii. Has a current history (within the past 90 days) of being prescribed Zeposia (ozanimod) (does not apply to non-preferred brands when the therapeutically equivalent generic is preferred or to non-preferred generics when the therapeutically equivalent brand is preferred)

See the Preferred Drug List (PDL) for the list of preferred Cytokine and CAM Antagonists at: https://papdl.com/preferred-drug-list;

AND

8. If a prescription for Zeposia (ozanimod) is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-

[1] Poor prognostic factors include initial diagnosis or clinical evidence supports the onset of symptoms at <40 years of age, extensive colitis, severe endoscopic disease (presence of large and/or deep ulcers), hospitalization for colitis, elevated inflammatory markers, low serum albumin, extra-intestinal manifestations, early need for corticosteroids (ACG 2019; AGA 2019; AGA 2020).

Dose-Limits.aspx.

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 ZEPOSIA (OZANIMOD): The determination of medical necessity of a request for renewal of a prior authorization for Zeposia (ozanimod) that was previously approved will take into account whether the beneficiary:

1. Is prescribed Zeposia (ozanimod) by or in consultation with an appropriate specialist (i.e., a neurologist for a diagnosis of multiple sclerosis or a gastroenterologist for a diagnosis of ulcerative colitis); **AND**

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

3. Does not have a contraindication to Zeposia (ozanimod); **AND**

4. For treatment of multiple sclerosis, has documented improvement or stabilization of the multiple sclerosis disease course; **AND**

5. For treatment of ulcerative colitis, experienced improvement in disease activity and/or level of functioning since starting Zeposia (ozanimod); **AND**

6. If a prescription for Zeposia (ozanimod) is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

   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 Zeposia (ozanimod). 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

1. Zeposia Package Insert. Summit, NJ: Celgene Corporation; May 2021.
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4. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline recommendations summary: Disease-modifying therapies for adults with multiple sclerosis: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. Neurology. 2018; 90:777.
5. Sandborn WJ, Feagan BG, Hanauer S, et al. Long-term efficacy and safety of ozanimod in moderately to severely active ulcerative colitis: results from the open-label extension of the randomized, phase 2 TOUCHSTONE study. J Crohns Colitis. 2021;15(7):1120-1129.
6. Cohen RD, Stein AC. Management of moderate to severe ulcerative colitis in adults. In: UpToDate [internet database]. Lamont JT, Robson KM, eds. Waltham, MA: UpToDate Inc. Updated August 23, 2021. Accessed August 26, 2021.
7. Harbord M, Eliakim R, Bettenworth D, et al. Third European evidence-based consensus on diagnosis and management of ulcerative colitis. Part 2: current management. J Crohns Colitis; 2017;11(7):769-784.
8. Rubin DT, Ananthakrishnan AN, Siegel CA, Sauer BG, Long MD. ACG clinical guideline: ulcerative colitis in adults. Am J Gastroenterol. 2019;114:384-413.
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