


ISSUE DATE November 27, 2023	EFFECTIVE DATE January 8, 2024	NUMBER *See below
SUBJECT Prior Authorization of Ulcerative Colitis Agents – Pharmacy Services		BY  Sally A. Kozak, Deputy Secretary Office of Medical Assistance Programs

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 Ulcerative Colitis Agents 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 medical necessity of Ulcerative Colitis Agents will be utilized in the fee-for-service and managed care delivery systems. Providers rendering services to MA beneficiaries in the managed care delivery system should address any questions related to the prior authorization of Ulcerative Colitis Agents to the appropriate managed care organization.

BACKGROUND/DISCUSSION:

The Department of Human Services (Department) is updating the medical necessity guidelines for Ulcerative Colitis Agents to include guidelines for sphingosine 1-phosphate

*01-23-54	09-23-53	27-23-44	33-23-51
02-23-42	11-23-42	30-23-45	
03-23-40	14-23-41	31-23-55	
08-23-57	24-23-50	32-23-40	

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>.

receptor (S1PR) modulators. Previously, Zeposia (ozanimod) was the only S1PR modulator approved by the U.S. Food and Drug Administration (FDA) for the treatment of ulcerative colitis. Recently, the FDA approved a second S1PR modulator, Velsipity (etrasimod), for this indication.

Guidelines for the use of Zeposia (ozanimod) for the treatment of ulcerative colitis were previously included in the prior authorization guideline specific to Zeposia (ozanimod). The guidelines for Zeposia (ozanimod) for the treatment of ulcerative colitis are now included in the Ulcerative Colitis Agents prior authorization guideline and apply to all S1PR modulators in the Ulcerative Colitis Agents Statewide Preferred Drug List class.

Zeposia (ozanimod) is also approved by the FDA for the treatment of multiple sclerosis. Requests for Zeposia (ozanimod) for the treatment of multiple sclerosis will be subject to the guidelines in the Multiple Sclerosis Agents prior authorization guideline.

In addition, the Department is clarifying that requests for all other non-preferred Ulcerative Colitis Agents will consider the beneficiary's diagnosis.

The revisions to the guidelines to determine medical necessity of prescriptions for Ulcerative Colitis Agents 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 Ulcerative Colitis Agents 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 Ulcerative Colitis Agents) 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 and products 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>

OBSOLETE:

The following bulletins, which are obsolete January 8, 2024, address the prior authorization of Zeposia (ozanimod), which is now outlined in the prior authorization guidelines for the Ulcerative Colitis Agents class on the Statewide PDL.

MA Bulletin 01-21-44, 02-21-31, 03-21-31, 08-21-46, 09-21-43, 11-21-33, 14-21-34, 24-21-41, 27-21-35, 30-21-38, 31-21-46, 32-21-31, 33-21-43, titled “Prior Authorization of Zeposia (ozanimod) – Pharmacy Services,” issued November 16, 2021.

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

I. Requirements for Prior Authorization of Ulcerative Colitis Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for Ulcerative Colitis Agents that meet any of the following conditions must be prior authorized:

1. A non-preferred Ulcerative Colitis Agent. See the Preferred Drug List (PDL) for the list of preferred Ulcerative Colitis Agents at: <https://papdl.com/preferred-drug-list>.
2. An Ulcerative Colitis Agent with a prescribed quantity that exceeds the quantity limit. 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>.
3. A prescription for a sphingosine 1-phosphate receptor (S1PR) modulator.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Ulcerative Colitis Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For an S1PR modulator, **one** of the following:
 - a. For treatment of multiple sclerosis, see the prior authorization guidelines related to Multiple Sclerosis Agents
 - b. For treatment of ulcerative colitis (UC), **all** of the following:
 - i. Is prescribed the requested medication 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,
 - ii. Is prescribed the requested medication by or in consultation with an appropriate specialist (e.g., a gastroenterologist),
 - iii. Does not have a contraindication to the requested medication,
 - iv. Is prescribed a dose that is consistent with the FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,
 - v. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,
 - vi. **Both** of the following:

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- a) Has **one** of the following:
 - (i) Mild UC that is associated with multiple poor prognostic factors¹
 - (ii) Moderate to severe UC

- b) **One** of the following:
 - (i) Failed to achieve remission with or has a contraindication or an intolerance to an induction course of corticosteroids,

 - (ii) **One** of the following:
 - a. 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.)
 - b. Has a contraindication or an intolerance to immunomodulators in accordance with current consensus guidelines,

 - (iii) **Both** of the following:
 - a. Has achieved remission with the requested medication
 - b. Will be using the requested medication as maintenance therapy to maintain remission

- vii. **One** of the following:
 - a) 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
 - b) Has a current history (within the past 90 days) of being prescribed the requested medication (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);

AND

- 2. For all other non-preferred Ulcerative Colitis Agents, **one** of the following:
 - a. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Ulcerative Colitis Agents approved or medically accepted for the beneficiary's diagnosis

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).

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- b. Has a current history (within the past 90 days) of being prescribed the same non-preferred Ulcerative Colitis Agent (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);

AND

3. If a prescription for an Ulcerative Colitis Agent 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.

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 AN S1PR MODULATOR: The determination of medical necessity of a request for renewal of a prior authorization for an S1PR modulator that was previously approved will take into account whether the beneficiary:

1. Is prescribed the requested medication by or in consultation with an appropriate specialist (e.g., gastroenterologist); **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 the requested medication; **AND**
4. Experienced improvement in disease activity and/or level of functioning since starting the requested medication; **AND**
5. If a prescription for the requested medication 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.

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 an Ulcerative Colitis Agent. 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

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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]. Princeton, NJ: Bristol-Myers Squibb Company; August 2023.
2. Velsipity [package insert]. New York, NY: Pfizer Labs; October 2023.
3. 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.
4. Rubin DT, Ananthakrishnan AN, Siegel CA, Sauer BG, Long MD. ACG clinical guideline: ulcerative colitis in adults. *Am J Gastroenterol*. 2019;114:384-413.
5. Ko CW, Singh S, Feuerstein JD, Falck-Ytter C, Falck-Ytter Y, Cross RK. AGA clinical practice guidelines on the management of mild-to-moderate ulcerative colitis. *Gastroenterology*. 2019;156:748-764.
6. Feuerstein JD, Isaacs KL, Schneider Y, Siddique SM, Falck-Ytter Y, Singh S. AGA clinical practice guidelines on the management of moderate to severe ulcerative colitis. *Gastroenterology*. 2020;158:1450-1461.
7. 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.