


<b>ISSUE DATE</b>  November 15, 2021	<b>EFFECTIVE DATE</b>  January 3, 2022	<b>NUMBER</b>  *See below
<b>SUBJECT</b>  Prior Authorization of Ulcerative Colitis Agents – Pharmacy Services		<b>BY</b>    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 the medical necessity of Ulcerative Colitis Agents 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 Ulcerative Colitis Agents to the appropriate MCO.

**BACKGROUND:**

*01-21-42	09-21-41	27-21-33	33-21-41
02-21-29	11-21-31	30-21-36	
03-21-29	14-21-32	31-21-44	
08-21-44	24-21-39	32-21-29	

**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 15, 2021, meeting, the P&T Committee recommended the following revisions to the guidelines to determine medical necessity of Ulcerative Colitis Agents:

- Addition of a guideline for Zeposia (ozanimod) that refers to the Zeposia (ozanimod) prior authorization guidelines and
- Clarification of the guidelines for a non-preferred Ulcerative Colitis Agent that a current history 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.

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

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. A prescription for Zeposia (ozanimod).
3. 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>.

**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 Zeposia (ozanimod), see the provider handbook pages in the SECTION II chapter related to Zeposia (ozanimod); **OR**
2. For a non-preferred Ulcerative Colitis Agent, **one** of the following:
  - a. Has a history of therapeutic failure, contraindication, or intolerance of the preferred Ulcerative Colitis Agents
  - 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.

**C. Clinical Review Process**

MEDICAL ASSISTANCE HANDBOOK  
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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 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.