


<b>ISSUE DATE</b>  August 21, 2019	<b>EFFECTIVE DATE</b>  January 1, 2020	<b>NUMBER</b>  *See below
<b>SUBJECT</b>  Prior Authorization of Vaginal Anti-Infectives – 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:  
[http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S\\_001994](http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S_001994).

**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 Vaginal Anti-Infectives submitted for prior authorization.

**SCOPE:**

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance (MA) Program and providing services in the fee-for-service delivery system. Providers rendering services in the MA managed care delivery system should address any questions related to Vaginal Anti-Infectives to the appropriate managed care organization.

**BACKGROUND:**

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

*01-19-30	09-19-28	27-19-26	33-19-28
02-19-25	11-19-24	30-19-24	
03-19-24	14-19-24	31-19-30	
08-19-33	24-19-26	32-19-24	

**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 Web site at  
<http://www.dhs.pa.gov/provider/healthcaremedicalassistance/index.htm>

- 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 May 15, 2019, meeting, the P&T Committee recommended renaming the Antibiotics, Vaginal PDL class of drugs to Vaginal Anti-Infectives. The committee also recommended revising the guidelines to determine medical necessity to reflect that U.S. Food and Drug Administration-approved indications and medically accepted uses will be taken into account when reviewing requests for non-preferred agents in this class.

The revisions to the PDL drug class and corresponding guidelines to determine medical necessity of Vaginal Anti-Infectives 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 Vaginal Anti-Infectives 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 Vaginal Anti-Infectives) 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

<http://www.dhs.pa.gov/provider/pharmacyservices/pharmacypriorauthorizationgeneralrequirements/index.htm>

Prior Authorization of Pharmaceutical Services Handbook – SECTION II

Pharmacy Prior Authorization Guidelines

<http://www.dhs.pa.gov/provider/pharmacyservices/drugsrequiringclinicalpriorauthorization/index.htm>

MEDICAL ASSISTANCE HANDBOOK  
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

**I. Requirements for Prior Authorization of Vaginal Anti-Infectives**

A. Prescriptions That Require Prior Authorization

All prescriptions for a non-preferred Vaginal Anti-Infective must be prior authorized.

See the Preferred Drug List (PDL) for the list of preferred Vaginal Anti-Infectives at:  
<https://papdl.com/preferred-drug-list>.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a non-preferred Vaginal Anti-Infective, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Has a documented history of therapeutic failure, contraindication, or intolerance of the preferred Vaginal Anti-Infectives approved or medically accepted for the beneficiary's diagnosis.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement 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 Vaginal Anti-Infective. 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.