


ISSUE DATE November 6, 2023	EFFECTIVE DATE January 8, 2024	NUMBER *See below
SUBJECT Prior Authorization of Antivirals, CMV – 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 Antivirals, CMV 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 Antivirals, CMV 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 Antivirals, CMV to the appropriate managed care organization.

BACKGROUND:

*01-23-33	09-23-32	27-23-23	33-23-30
02-23-21	11-23-21	30-23-24	
03-23-19	14-23-20	31-23-34	
08-23-36	24-23-29	32-23-19	

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

DISCUSSION:

During the September 12, 2023, meeting, the P&T Committee recommended revisions to the medical necessity guidelines for Antivirals, CMV to address the recent approval by the U.S. Food and Drug Administration of Prevmis (Itermovir) for CMV prophylaxis in kidney transplant recipients.

The revisions to the guidelines to determine medical necessity of prescriptions for Antivirals, CMV 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 Antivirals, CMV 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 Antivirals, CMV) 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>

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

I. Requirements for Prior Authorization of Antivirals, CMV

A. Prescriptions That Require Prior Authorization

Prescriptions for Antivirals, CMV that meet any of the following conditions must be prior authorized:

1. A non-preferred Antiviral, CMV. See the Preferred Drug List (PDL) for the list of preferred Antivirals, CMV at: <https://papdl.com/preferred-drug-list>.
2. An Antiviral, CMV 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 letermovir.

B. Review of Documentation for Medical Necessity

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

1. Is prescribed the Antiviral, CMV 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 age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
3. Is prescribed a dose and duration of therapy that are consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
4. Does not have a contraindication to the requested medication; **AND**
5. For letermovir, **all** of the following:
 - a. Is prescribed letermovir by or in consultation with an appropriate specialist (i.e., hematologist/oncologist, infectious disease specialist, or transplant specialist),
 - b. **One** of the following in accordance with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature:
 - i. Is CMV-seropositive

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

- ii. Is at high risk for CMV reactivation,
- c. **One** of the following:
 - i. Is prescribed letermovir for continuation of treatment upon inpatient discharge
 - ii. Will initiate treatment with letermovir in the post-transplant period in accordance with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature;

AND

- 6. For maribavir, **all** of the following:
 - a. Is prescribed maribavir by or in consultation with an appropriate specialist (i.e., hematologist/oncologist, infectious disease specialist, or transplant specialist),
 - b. If currently taking ganciclovir or valganciclovir, will discontinue ganciclovir or valganciclovir prior to starting maribavir,
 - c. For treatment of post-transplant CMV infection/disease, **one** of the following:
 - i. Is prescribed maribavir for continuation of treatment upon inpatient discharge,
 - ii. Has a history of therapeutic failure of or a contraindication or an intolerance to at least **one** of the following:
 - a) Ganciclovir,
 - b) Valganciclovir,
 - c) Cidofovir,
 - d) Foscarnet,
 - iii. Has culture and sensitivity results documenting that only maribavir will be effective;

AND

- 7. For all other non-preferred Antivirals, CMV, **one** of the following:
 - a. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Antivirals, CMV approved or medically accepted for the beneficiary's diagnosis or indication
 - b. Has culture and sensitivity results showing **both** of the following:
 - i. The beneficiary's infection is not susceptible to the preferred Antivirals, CMV

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

- ii. The beneficiary's infection is susceptible to the requested non-preferred Antiviral, CMV;

AND

- 8. If a prescription for an Antiviral, CMV 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 Antiviral, CMV. 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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MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

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