



ISSUE DATE November 8, 2022	EFFECTIVE DATE January 9, 2023	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:

*01-22-53	09-22-52	27-22-40	33-22-50
02-22-37	11-22-37	30-22-43	
03-22-36	14-22-37	31-22-56	
08-22-61	24-22-45	32-22-37	

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

DISCUSSION:

During the September 13, 2022, meeting, the P&T Committee recommended the following revisions to the guidelines to determine medical necessity of Antivirals, CMV:

- Addition of a guideline that the Antiviral, CMV is prescribed 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.
- Addition of a guideline that the beneficiary is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature.
- Addition of a guideline that the beneficiary is prescribed a dose and duration of therapy that are consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature.
- Addition of a guideline that the beneficiary does not have a contraindication to the requested medication.
- Revision of the guidelines for Ietermovir.
- Addition of guidelines to address the recent FDA approval of maribavir for the treatment of post-transplant CMV infection/disease that is refractory to treatment with ganciclovir, valganciclovir, cidofovir, or foscarnet.
- Addition of a guideline for non-preferred Antivirals, CMV that considers results of culture and sensitivity testing.
- Removal of the duration of approval section.

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>

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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. A prescription for letermovir.
3. 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>.

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. Has received a hematopoietic stem cell transplant,
 - c. **One** of the following:

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- i. Is CMV-seropositive
 - ii. Is at high risk for CMV reactivation,
- d. For primary prophylaxis of CMV infection/disease after allogeneic hematopoietic stem cell transplant, will initiate or has initiated treatment with letermovir between day 0 and day 28 post-transplant;

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

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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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