pennsylvania
DEPARTMENT OF HUMAN SERVICES

MEDICAL ASSISTANCE BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
August 20, 2019	January 1, 2020	*See below

SUBJECT

Prior Authorization of Antivirals, CMV – Pharmacy Services

BY

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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.

PURPOSE:

The purpose of this bulletin is to:

1. Inform providers of the addition of the Antivirals, CMV class of drugs to the Preferred Drug List (PDL).
2. Issue new 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 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 Antivirals, CMV to the appropriate managed care organization.

BACKGROUND:

*01-19-36	09-19-34	27-19-32	33-19-34
02-19-31	11-19-30	30-19-30	
03-19-30	14-19-30	31-19-36	
08-19-39	24-19-32	32-19-30	

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

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

- Preferred or non-preferred status for new drugs in therapeutic classes already included in the 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 that the Department add the Antivirals, CMV class of drugs to the PDL and proposed guidelines to determine medical necessity of Antivirals, CMV. The requirement for prior authorization and guidelines to determine medical necessity of Antivirals, CMV, 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 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

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 Prevymis (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: http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm.

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. For a non-preferred Antiviral, CMV, has a history of therapeutic failure, intolerance, or contraindication of the preferred Antivirals, CMV approved for the beneficiary's diagnosis or indication; **AND**

2. For Prevymis (letermovir), **all** of the following:

   a. Is prescribed Prevymis (letermovir) for prophylaxis of cytomegalovirus (CMV) infection and disease,

   b. Is age-appropriate according to U.S. Food and Drug Administration (FDA)-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,

   c. Is prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,

   d. Is prescribed Prevymis (letermovir) by or in consultation with an appropriate specialist (ie, hematologist/oncologist, infectious disease specialist, or transplant specialist),

   e. Had all potential drug interactions addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the interacting drug, or

counseling of the beneficiary of the risks associated with the use of both medications when they interact),

f. Does not have a history of a contraindication to Prevymis (letermovir),

g. Has received an allogeneic hematopoietic stem cell transplant,

h. Is CMV-seropositive,

i. Is at high risk for CMV reactivation,

j. Does not have evidence of CMV replication as demonstrated by antigenemia or polymerase chain reaction (PCR),

k. Will initiate or has initiated treatment with Prevymis (letermovir) between day 0 and day 28 post-transplantation;

AND

3. If a prescription for an Antiviral, CMV is in 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 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. Dose and Duration of Therapy

Requests for prior authorization of Prevymis (letermovir) for prophylaxis of CMV infection and disease following allogeneic hematopoietic stem cell transplant will be approved for up to 100 days following the date of transplant.

D. 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.

E. References

1. Prevymis [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; March 2019.
2. Marty FM, Ljungman P, Chemaly RF, et al. Letermovir prophylaxis for cytomegalovirus in hematopoietic-cell transplantation. N Engl J Med. 2017;377:2433-2444.
3. Tomblyn M, Chiller T, Einsele H, et al. Guidelines for preventing infectious complications among hematopoietic cell transplant recipients: a global perspective. Biol Blood Marrow Transplant. 2009;15(10):1143-1238.
4. Chen K, Cheng MP, Hammond SP, Einsele H, Marty FM. Antiviral prophylaxis for cytomegalovirus infection in allogeneic hematopoietic cell transplantation. Blood Adv. 2018;2(16):2159-2175.
5. Ljungman P, Hakki M, Boeckh M. Cytomegalovirus in hematopoietic stem cell transplant recipients. Hematol Oncol Clin North Am. 2011;25(1):151-169.
6. Wingard JR. Prevention of viral infections in hematopoietic cell transplant recipients. Marr KA, Thorner AR, eds. Waltham, MA: UpToDate Inc. Updated January 9, 2019. Accessed May 3, 2019.
7. Ljungman P, Lazarus HM. Optimal management approach to prevent cytomegalovirus infection in patients undergoing allogeneic hematopoietic cell transplantation. The Hematologist. 2018;15(2):4-5. https://www.hematology.org/Thehematologist/Ask/8277.aspx. Accessed May 3, 2019.