Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: N/A**
Policy Number: PHW.PDL.735	**Effective Date: 01/01/2020** **Revision Date: 01/2021**
Policy Name: Antivirals, CMV	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ☐ **Revised Policy***
- ✓ **Annual Review - No Revisions**
- ✓ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

Q1 2021 annual review: no changes.

Name of Authorized Individual (Please type or print): **Auren Weinberg, MD**	**Signature of Authorized Individual:** 

Clinical Policy: Antivirals, CMV

Reference Number: PHW.PDL.735
Effective Date: 01/01/2020
Last Review Date: 01/2021

Revision Log

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with PA Health and Wellness® that Antivirals, CMV are **medically necessary** when the following criteria are met:

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.

2. A prescription for Prevymis (letermovir).

3. An Antiviral, CMV with a prescribed quantity that exceeds the quantity limit.

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 PA.CP.PMN.59 Quantity Limit Override.

   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 **100 days** following the date of transplant.

For requests for all other **non-preferred CMV antivirals: 12 months**

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.

Reviews, Revisions, and Approvals	Date
Policy created	01/01/2020
Q3 2020 annual review: no changes.	07/2020
Q1 2021 annual review: no changes.	01/2021