Highmark Wholecare
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

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.

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

   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.

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ANTIVIRALS, CMV PRIOR AUTHORIZATION FORM *(form effective 1/8/2024)*

☐New request ☐Renewal request	# of pages: _____	Prescriber name:	
Name of office contact:		Specialty:	
Contact's phone number:		NPI:	State license #:
LTC facility contact/phone:		Street address:	
Beneficiary name:		City/state/zip:	
Beneficiary ID#:	DOB:	Phone:	Fax:

CLINICAL INFORMATION

Drug requested:	Strength:	Dosage form:	
Directions:		Quantity:	Refills:
Diagnosis (*submit documentation*):		Diagnosis code (*required*):	
Is the requested medication being prescribed by or in consultation with a hematologist/oncologist, infectious disease specialist, or transplant specialist?		☐Yes ☐No	*Submit documentation of consultation.*

Complete all sections that apply to the beneficiary and this request. *Check all that apply and submit documentation for each item.*

1. For Livtencity (maribavir):
- ☐The beneficiary is/was taking ganciclovir or valganciclovir AND:
  - ☐Ganciclovir/valganciclovir will be/was discontinued before starting Livtencity (maribavir)
- ☐Is being treated for post-transplant CMV infection/disease AND:
  - ☐Is continuing treatment with Livtencity (maribavir) upon inpatient discharge
  - ☐Tried and failed or has a reason not to try at least one of the following:
    - ☐cidofovir ☐foscarnet ☐ganciclovir ☐valganciclovir
  - ☐Has culture and sensitivity results showing that only Livtencity (maribavir) will be effective
- ☐Is receiving concomitant therapy with carbamazepine OR phenobarbital AND:
  - ☐The dose of Livtencity (maribavir) was adjusted according to FDA-approved package labeling

2. For Prevymis (letermovir):
- ☐Is using Prevymis (letermovir) for post-transplant CMV prophylaxis AND:
  - ☐Is CMV-seropositive
  - ☐Is at high risk for CMV reactivation (eg, cord blood transplant, CMV-seropositive donor)
- ☐Is NOT receiving concomitant therapy with a contraindicated drug/drug combination (eg, ergot alkaloids, pimozide, pitavastatin with cyclosporine, simvastatin with cyclosporine)
- ☐Is or will be receiving concomitant therapy with cyclosporine AND:
  - ☐The dose of Prevymis (letermovir) was adjusted according to FDA-approved package labeling
- ☐Initiated or will initiate treatment with Prevymis (letermovir) in the post-transplant period in accordance with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature
- ☐Is continuing treatment with Prevymis (letermovir) upon inpatient discharge

3. For all other NON-PREFERRED Antivirals, CMV:
- ☐Has a history of trial and failure of or a contraindication or an intolerance to the preferred Antivirals, CMV approved or medically accepted for the beneficiary's diagnosis or condition *(Refer to https://papdl.com/preferred-drug-list for a list of preferred and non-preferred drugs in this class.)*
- ☐Has culture and sensitivity results showing BOTH of the following:
  - ☐The beneficiary's infection is NOT susceptible to the preferred Antivirals, CMV
  - ☐The beneficiary's infection IS susceptible to the requested non-preferred Antivirals, CMV

PLEASE FAX COMPLETED FORM TO HIGHMARK WHOLECARE – PHARMACY DIVISION

Prescriber Signature:	**Date**: