PA DEPARTMENT OF HUMAN SERVICES
MAAC BRIEFING DOCUMENT
ANTIVIRALS, CMV

**Proposed Effective Date:** January 1, 2020

## 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 being prescribed Prevymis (letermovir) for prophylaxis of cytomegalovirus (CMV) infection and disease,

   b. Is CMV-seropositive,

   c. Has received an allogeneic hematopoietic stem cell transplant,

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

   e. Is at high risk for CMV reactivation,

   f. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,

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

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

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

j. 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),

k. Does not have a history of a contraindication to Prevymis (letermovir);

**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 the request for 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.