Clinical Policy: Antivirals, CMV

Reference Number: PHW.PDL.735
Effective Date: 01/01/2020
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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 PA Health & 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 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. 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 (ie, hematologist/oncologist, infectious disease specialist, or transplant specialist),

b. Has received hematopoietic stem cell transplant,

c. One of the following:
   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-transplantation;

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;
      AND

7. 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:

For up to **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 2020.
2. Livtencity [package insert]. Lexington, MA: Takeda Pharmaceuticals America, Inc. November 2021.
3. Marty FM, Ljungman P, Chemaly RF, et al. Letermovir prophylaxis for cytomegalovirus in hematopoietic-cell transplantation. N Engl J Med. 2017;377:2433-2444.
4. Avery RK, Alain S, Alexander BD, et al. Maribavir for refractory cytomegalovirus infections with or without resistance post-transplant: Results from a phase 3 randomized clinical trial [published online ahead of print December 2, 2021]. Clin Infect Dis. doi.org/10.1093/cid/ciab988.
5. 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.
6. Wingard JR. Prevention of viral infections in hematopoietic cell transplant recipients. In: UpToDate [internet database]. Bow E, Bond S, eds. Waltham, MA: UpToDate Inc. Updated November 29, 2021. Accessed April 15, 2022.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.

7. Hakki M, Aitken SL, Danziger-Isakov L, et al. American Society for Transplantation and Cellular Therapy series: #3 – Prevention of cytomegalovirus infection and disease after hematopoietic cell transplantation. Transplant Cell Ther. 2021;27(9):707-719. doi: 10.1016/j.jtct.2021.05.001.
8. Yong MK, Shigle TL, Kim YJ, Carpenter PA, Chemaly RF, Papanicolaou GA. American Society of Transplantation and Cellular Therapy series, 4#: Cytomegalovirus treatment and management of resistant or refractory infections after hematopoietic cell transplantation. Transplant Cell Ther. 2021;27(12):957-967. doi.org/10.1016/j.jtct.2021.09.010.
9. Olson AL, Politikos I, Brunstein C, Milano F, Barker J, Hill JA. Guidelines for infection prophylaxis, monitoring and therapy in cord blood transplantation. Transplant Cell Ther. 2021;27(5):359-362. doi.org/10.1016/j.jtct.2021.01.024.
10. Robin C, Thiebaut A, Alain S, et al. Letermovir for secondary prophylaxis of cytomegalovirus infection and disease after allogeneic hematopoietic cell transplantation: Results from the French Compassionate Program. Biol Blood Marrow Transplant. 2020;26(5):978-984. doi: 10.1016/j.bbmt.2020.01.027.
11. Cassaniti I, Colombo AA, Bernasconi P, et al. Positive HCMV DNAemia in stem cell recipients undergoing letermovir prophylaxis is expression of abortive infection. Am J Transplant. 2021;21:1622-1628.

Reviews, Revisions, and Approvals	Date
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Q1 2021 annual review: no changes.	01/2021
Q1 2023: policy revised according to DHS revisions effective 01/09/2023.	10/2022