Clinical Policy: Antivirals, CMV

Reference Number: PHW.PDL.735
Effective Date: 01/01/2020
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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. An Antiviral, CMV with a prescribed quantity that exceeds the quantity limit.

3. 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 member:

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 member's diagnosis or indication

    b. Has culture and sensitivity results showing **both** of the following:

        i. The member's infection is not susceptible to the preferred Antivirals, CMV
        ii. The member's infection is susceptible to the requested non-preferred Antiviral, CMV;

    AND

8. 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 member 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 member, 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 member.

E. References

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12. 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.
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Reviews, Revisions, and Approvals	Date
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Q3 2020 annual review: no changes.	07/2020
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Q1 2023: policy revised according to DHS revisions effective 01/09/2023.	10/2022
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Q1 2025 annual review: no changes.	11/2024