Applicable Drugs: Prevymis (letermovir)

Preferred: N/A

Non-preferred: N/A

Date of Origin: 5/23/2019

Date Last Reviewed / Revised: 10/23/2026

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I to IV are met)

I. Documented diagnosis of one of the following conditions A or B and must meet ALL criteria listed under the applicable diagnosis:

   A. Prophylaxis of cytomegalovirus (CMV) infection and disease in CMV-seropositive recipient (R+) of an allogeneic hematopoietic stem cell transplant (HSCT):

      i. Age 6 months or older weighing at least 6 kg (13.2 lbs)

      ii. Treatment will be initiated no later than 28 days post-HSCT

   B. Prophylaxis of cytomegalovirus (CMV) infection and disease in kidney transplant recipient at high risk (Donor CMV seropositive/Recipient CMV seronegative [D+/R-]):

      i. Age 12 years or older weighing at least 40 kg (88.2 lbs)

      ii. Treatment will be initiated no later than 7 days post-transplant.

      iii. Treatment failure or contraindication to valganciclovir.

II. Prescriber is an oncologist, hematologist, transplant, or infectious disease specialist.

III. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

IV. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product(s).

EXCLUSION CRITERIA

- Severe hepatic impairment (Child-Pugh C).
- Concomitant use with:
  - Pimozide
  - Ergot alkaloids
  - Pitavastatin and simvastatin when co-administered with cyclosporine

OTHER CRITERIA

- Oral formulations are preferred over injectable formulations. Approval of intravenous formulation requires documented clinical rationale demonstrating medical necessity of the intravenous formulation compared to both the oral tablet and pellet packet formulations.

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Adult and pediatric patients 12 years of age and older weighing at least 30 kg for HSCT or at least 40 kg for kidney transplant:
    - **Without** concomitant cyclosporine
        - Tablet: Twenty-eight 480 mg tablets per 28 days **OR**
        - Oral pellets: One hundred twenty (120) 120 mg packets per 30 days **OR**
        - Injection: Twenty-eight 480 mg/24 mL single-dose vials (672 total mL) per 28 days
    - **With** concomitant cyclosporine
        - Tablet: Twenty-eight 240 mg tablets per 28 days **OR**
        - Oral pellets: Sixty (60) 120 mg packets per 30 days **OR**
        - Injection: Twenty-eight 240 mg/12 mL single-dose vials (336 total mL) per 28 days
- Pediatric HSCT recipients 6 months to less than 12 years of age, or 12 years of age and older weighing less than 30 kg:
    - **Without** concomitant cyclosporine
        - 15 kg to less than 30 kg
            - Tablet: Twenty-eight 240 mg tablets per 28 days **OR**
            - Oral pellets: Sixty (60) 120 mg packets per 30 days **OR**
            - Injection: Twenty-eight 240 mg/12 mL single-dose vials (336 total mL) per 28 days
        - 7.5 kg to less than 15 kg
            - Oral pellets: Thirty (30) 120 mg packets per 30 days **OR**
            - Injection: Twenty-eight 240 mg/12 mL single-dose vials (336 total mL) per 28 days
            - Tablets not recommended
        - 6 kg to less than 7.5 kg
            - Oral pellets: One hundred twenty (120) 20 mg packets per 30 days **OR**
            - Injection: Twenty-eight 240 mg/12 mL single-dose vials (336 total mL) per 28 days

- Tablets not recommended

- **With** concomitant cyclosporine
  - Tablets are not recommended for these patients in any listed weight category.
  - 15 kg to less than 30 kg
    - Oral pellets: Thirty (30) 120 mg packets per 30 days
    - Injection: Twenty-eight 240 mg/12 mL single-dose vials (336 total mL) per 28 days
  - 7.5 kg to less than 15 kg
    - Oral pellets: Ninety (90) 20 mg packets per 30 days
    - Injection: Twenty-eight 240 mg/12 mL single-dose vials (336 total mL) per 28 days
  - 6 kg to less than 7.5 kg
    - Oral pellets: Sixty (60) 20 mg packets per 30 days
    - Injection: Twenty-eight 240 mg/12 mL single-dose vials (336 total mL) per 28 days

APPROVAL LENGTH

- **Authorization:**
  - HSCT: through 100 days post-transplant date.
    - In patients at risk for late CMV infection and disease, treatment may be continued through 200 days post-HSCT. Clinical justification must be provided.
  - Kidney transplant: through 200 days post-transplant date.
- **Re-Authorization:** Requests for additional courses of Prevymis may be approved for patients undergoing an additional HSCT/kidney transplant, if medical necessity criteria are met.

APPENDIX

N/A

REFERENCES

1. Prevymis. Prescribing information. Pfizer, Inc.; 2026. Accessed October 23, 2026. https://www.merck.com/product/usa/pi_circulars/p/prevymis/prevymis_pi.pdf
2. NCCN Clinical Practice Guidelines in Oncology for prevention and treatment of cancer-related infections. V1.2026. Accessed October 23, 2026. https://www.nccn.org/professionals/physician_gls/pdf/infections.pdf

3. 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
4. Hayden RT, , Kotton CN, et al. The Fourth International Consensus Guidelines on the Management of Cytomegalovirus in Solid Organ Transplantation. 2025;109(7):1066-1110. doi:10.1097/TP.0000000000005374
5. Limaye AP, Budde K, Humar A, et al. Letermovir vs Valganciclovir for Prophylaxis of Cytomegalovirus in High-Risk Kidney Transplant Recipients: A Randomized Clinical Trial. *JAMA*. 2023;330(1):33-42. doi:10.1001/jama.2023.9106

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.