Generic Name: Letermovir

Applicable Drugs: Prevymis™

Preferred: N/A

Non-preferred: N/A

Date of Origin: 5/23/2019

Date Last Reviewed / Revised: 10/9/2023

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through VI are met)

I. Meets one of the following criteria for prophylaxis of cytomegalovirus (CMV) infection/disease:
   A. CMV-seropositive recipient (R+) of an allogeneic hematopoietic stem cell transplant (HSCT)
   B. Kidney transplant recipient at high risk (Donor CMV seropositive/Recipient CMV seronegative [D+/R-])

II. Age: ≥ 18 years old.

III. Initiation of treatment no later than 28 days post-transplantation for HSCT patients, or 7 days post-transplantation for kidney transplant patients.

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

V. Medication is prescribed in accordance with FDA labeling or current clinical practice guidelines.

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

EXCLUSION CRITERIA

- Severe hepatic impairment (Child-Pugh C).
- Concomitant use with pimozide, ergot alkaloids, and pitavastatin or simvastatin when co-administered with cyclosporine.

OTHER CRITERIA

- Prevymis oral tablets are preferred over the injectable formulation. Clinical justification must be provided supporting the medical necessity of the intravenous formulation over the oral formulation.

QUANTITY / DAYS SUPPLY RESTRICTIONS

- With concomitant cyclosporine

- Twenty-eight 240mg tablets per 28 days
- Thirty 240mg/12 mL single-dose vials per 30 days

- Without concomitant cyclosporine
  - Twenty-eight 480mg tablets per 28 days
  - Thirty 480mg/24 mL single-dose vials per 30 days

APPROVAL LENGTH

- **Authorization:**
  - HCST: through 100 days post-transplant date.
    - In patients at risk for late CMV infection and disease, Prevymis™ 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.

APPENDIX

N/A

REFERENCES

1. Prevymis. Prescribing information. Pfizer, Inc.; 2023. Accessed October 9, 2023. 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. V1.2023. Accessed October 9, 2023. 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

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.