Effective Date: 9/2019
Last Reviewed: 9/2019, 1/2020, 11/2020, 4/2021, 03/2022, 03/2023, 09/2023, 12/2023 Pharmacy Scope: Medicaid Medical Scope: Medicaid, Commercial, Medicare-Medicaid Plan (MMP)

PREVYMIS (letermovir) tablets and intravenous injection

MEDICAL POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendia uses are considered a covered benefit provided that all the approval criteria are met, and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

1. Prevymis is indicated for prophylaxis of cytomegalovirus (CMV) infection and disease in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT).

2. Prevymis is indicated for prophylaxis of CMV disease in adult kidney transplant recipients at high risk (Donor CMV seropositive/Recipient CMV seronegative [D+/R-]).

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR APPROVAL

An authorization may be granted when the following criteria are met:

- Member is 18 years of age or older; AND
- The requested drug is being prescribed for the prophylaxis of cytomegalovirus (CMV) infection and disease in an adult CMV-seropositive recipient [R+] of an allogenic hematopoietic stem cell transplant (HSCT) [Documentation must be provided of date of allogenic HSCT], OR
- The requested drug is being prescribed for prophylaxis of CMV disease in adult kidney transplant recipients at high risk (Donor CMV seropositive/Recipient CMV seronegative [D+/R-]). [Documentation must be provided of date of transplant]; AND
- The requested drug must be given within 100 days post-transplant; AND
- If requesting the IV formulation, documentation that the member must not be able to tolerate/swallow the oral tablet; AND
- MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements

III. DOSING LIMITS

- Prevymis 240mg and 480mg tablet: 1 tablet per day
- Prevymis inj 240mg/12ml: 12 ml per day (1 vial per day)
- Prevymis inj 480mg/24ml: 24 ml per day (1 vial per day)

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IV. COVERAGE DURATION

- Limited to a maximum of 100 days post-transplant

Per §§ 42 CFR 422.101, this clinical medical policy only applies to INTEGRITY in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD)

V. APPLICABLE CODES

The following HCPCS/CPT codes are:

HCPCS/CPT Code	Description
J3490	Unclassified drugs
C9399	Unclassified drugs or biologicals

VI. REFERENCES

1. Prevymis [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; August 2023. Accessed November 2023.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2023. https://online.lexi.com. Accessed June 16, 2023.
3. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 06/16/2023).