Letermovir injection (Prevymis®)	Place of Service Office Administration Infusion Center Administration Home Infusion Administration Hospital Administration Outpatient Facility Administration* *[*Prior authorization required – see section (1)]* HCPCS: J3490 NDC: • 0006-5003-01: 240 mg/12 mL (20 mg/mL) single-dose vial • 0006-5004-01: 480 mg/24 mL (20 mg/mL) single-dose vial

Condition listed in policy (*see criteria for details*)

- Cytomegalovirus (CMV) prophylaxis in adult CMV-seropositive recipients of an allogeneic hematopoietic stem cell transplant (HSCT)

AHFS therapeutic class: Antiviral

Mechanism of action: CMV DNA terminase complex inhibitor

(1) Special Instructions and pertinent Information

Covered under the medical benefit, please submit clinical information for prior authorization review.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for letermovir injection (Prevymis®) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Prophylaxis of Cytomegalovirus (CMV) infection and disease in CMV-seropositive recipients of an allogeneic hematopoietic stem cell transplant (HSCT)

1. Being used as prophylaxis of CMV infection and disease, **AND**
2. Either of the following:
    a. Recipient of an allogeneic HSCT and all the following:
        i. Diagnosis of CMV-seropositive, **AND**
        ii. Being used within 100 days post-transplant

    OR

    b. Recipient of a kidney transplant and all of the following:
        i. High risk (Donor CMV seropositive/Recipient CMV seronegative [D+/R-]), and
        ii. Being used within 200 days post-transplant

    AND
3. Medical reason why the oral formulation of Prevymis cannot be used

Covered Dose:
Up to 480 mg given as an IV infusion once daily

Coverage Period

HSCT: 100 days post-transplant
Kidney transplant: 200 days post-transplant

ICD-10:
B25 (CMV), Z94.81 (bone marrow transplant status)

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for letermovir injection (Prevymis®) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:

- 240 mg/12 mL (20 mg/mL) single-dose vial
- 480 mg/24 mL (20 mg/mL) single-dose vial

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- Prevymis® (letermovir) [Prescribing information]. Rahway, NJ: Merck & Co.; 6/2023.

(7) Policy Update

Date of last revision: 3Q2023
Date of next review: 1Q2024
Changes from previous policy version:

- Section (2): Prophylaxis of Cytomegalovirus (CMV) infection – Added coverage for prevention of CMV in high-risk kidney transplant recipients

  Rationale: In June 2023, FDA approved Prevymis for prophylaxis of CMV disease in adult kidney transplant recipients at high risk [D+/R-]

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee