Letermovir injection (Prevymis™)	**Place of Service** **Office Administration** **Infusion Center Administration** **Home Infusion Administration** **HCPC**: 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 via fax.

****CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION ****

AAAAI Guidelines 2011, MCG™ Care Guidelines, 19th edition, 2015

Members with the following benefits: **PPO, Direct Contract HMO, and when applicable, ASO/Shared Advantage,** may be required to have their medication administered at a preferred site of service, including the home, a physician's office, or an independent infusion center not associated with a hospital.

For members that cannot receive infusions in the preferred home or ambulatory setting AND meet one of the following criteria points, drug administration may be performed at a hospital outpatient facility infusion center.

****CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION ****

ADMINISTRATION OF PREVYMIS IN THE HOSPITAL OUTPATIENT FACILITY SITE OF CARE REQUIRES ONE OF THE FOLLOWING: (*Supporting Documentation must be submitted)*

1. **Patient is receiving their first infusion of Prevymis or is being re-initiated on Prevymis after at least 6 months off therapy.** *Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.*

Additional clinical monitoring is required during administration as evidenced by one of the following:

2. **Patient has experienced a previous severe adverse event to Prevymis based on documentation submitted.**

3. **Patient continues to experience moderate to severe adverse events to Prevymis based on documentation submitted, despite receiving premedication such as acetaminophen, steroids, diphenhydramine, fluids, etc.**

4. **Patient is clinically unstable based on documentation submitted.**

5. **Patient is physically or cognitively unstable based on documentation submitted.**

(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)

- Not being covered under the case rate (BSC reviewer to check with BSC Medical Management BMT Coordinator to see if med is covered under the case rate), and
- Recipient of an allogeneic HSCT, and
- Diagnosis of CMV-seropositive, and
- Being used as prophylaxis of CMV infection and disease, and
- Being used within 100 days post-transplant, and
- Medical reason why the oral formulation of Prevymis cannot be used

Covered Dose:
Up to 480mg once-daily IV. Initiate Prevymis between Day 0 and Day 28 post-transplantation, and continue through Day 100 post-transplant

Coverage Period
Up to Day 100 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)

Blue Shield's research indicates there is inadequate clinical evidence to support off-label use of this drug for the following conditions (Health and Safety Code 1367.21):

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

- Prevymis™ prescribing information. Merck & Co, Whitehouse Station, NJ. 2017.
- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch

(7) Policy Update

Date of initial review: 1Q2018
Date of next review: 1Q2019
Changes from previous policy version:

- New policy (1Q2018)

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