letermovir injection (Prevymis)

Commercial Medical Benefit Drug Policy

Place of Service
Office Administration
Infusion Center Administration
Home Infusion Administration
Hospital Administration
Outpatient Facility Administration

Drug Details

USP Category: ANTIVIRALS
Mechanism of Action: CMV DNA terminase complex inhibitor
HCPCS:
C9399:Unclassified drugs or biologicals
J3490:Unclassified drugs
How Supplied:

- 240 mg/12 mL (20 mg/mL) single-dose vial (NDC 0006-5003-01)
- 480 mg/24 mL (20 mg/mL) single-dose vial (NDC 0006-5004-01)

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

- Cytomegalovirus (CMV) Prophylaxis

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

Members with the following plans: **PPO, Direct Contract HMO, and when applicable, ASO, Shared Advantage, HMO (non-direct)** 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

MCG Care Guidelines, 19th edition, 2015

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

1. Patient is initiating therapy with Prevymis (allow for first two weeks) 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.*

OR

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

2. Patient has experienced a previous severe adverse event on Prevymis based on documentation submitted.
3. Patient continues to experience moderate to severe adverse events on 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.

Coverage Criteria
The following condition(s) require Prior Authorization/Preservice.

Cytomegalovirus (CMV) Prophylaxis

Meets medical necessity if all the following are met:

1. Not being covered under the case rate
2. Being used as prophylaxis of CMV infection and disease
3. Meets EITHER of the following:
   a. Recipient of an allogeneic HSCT and meets ALL of the following:
      i. Diagnosis of CMV-seropositive
      ii. Either of the following:
         1. Being used within 100 days post-transplant
         2. Being used through day 200 post-HSCT in patients at risk for late CMV infection and disease
   b. Recipient of a kidney transplant and meets ALL of the following:
      i. High risk (Donor CMV seropositive/Recipient CMV seronegative [D+/R-])
      ii. Being used within 200 days post-transplant
4. Medical reason why the oral formulation of Prevymis cannot be used

Covered Doses:

Up to 480 mg given as an intravenous infusion once daily

Coverage Period:

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

ICD-10:
Z94.81

Additional Information

Pediatric dosing for HSCT recipients

Recommended daily IV dosage of Prevymis in pediatric HSCT recipients 6 months to less than 12 years of age or 12 yeasts of age and older and weighing less than 30 kg (from Prescribing Information)

Body weight	Daily IV dose
30 kg and above	480 mg
15 kg to less than 30 kg	120 mg
7.5 kg to less than 15 kg	60mg
6 kg to less than 7.5 kg	40 mg

Recommended daily oral dosage of Prevymis in pediatric HSCT recipients 6 months to less than 12 years of age or 12 years of age and older and weighing less than 30 kg (from Prescribing Information)

Body weight	Daily oral dose	Tablets	Oral Pellets *(product availability pending)*
30 kg and above	480 mg	One 480 mg tablet or two 240 mg tablets	Four 120 mg packets of oral pellets
15 kg to less than 30 kg	120 mg	One 240 mg tablet	Two 120 mg packets of oral pellets
7.5 kg to less than 15 kg	60mg	Not recommended	One 120 mg packet of oral pellets
6 kg to less than 7.5 kg	40 mg	Not recommended	Four 20 mg packets of oral pellets

References

1. AHFS. Available by subscription at http://www.lexi.com
2. DrugDex. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
3. National Comprehensive Cancer Network. Prevention and Treatment of Cancer-Related Infections (Version 3.2024). Available at http://www.nccn.org.
4. Prevymis (letermovir) Prescribing Information. Merck & Co., Rahway, NJ: 2024.

Review History

Date of Last Annual Review: 1Q2025
Changes from previous policy version:

- No clinical change following annual review.

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee