# DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

**POLICY:** Infectious Disease – Prevymis Drug Quantity Management Policy – Per Days
- Prevymis™ (letermovir tablets – Merck Sharp & Dohme)

**REVIEW DATE:** 10/23/2024

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***INSTRUCTIONS FOR USE***

*THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.*

## CIGNA NATIONAL FORMULARY COVERAGE:

### OVERVIEW

Prevymis is an antiviral drug indicated for:[1]
- **Cytomegalovirus (CMV) prophylaxis** of infection and disease in adult and pediatric patients ≥ 6 months and weighing ≥ 6 kg who are CMV-seropositive recipients [R+] of an allogeneic **hematopoietic stem cell transplant** (HSCT).
- **CMV prophylaxis** of disease in adult and pediatric patients ≥ 12 years of age and weighing ≥ 40 kg who are **kidney transplant recipients** at high risk (donor CMV seropositive/recipient CMV seronegative [D+/R-].

### Dosing

- **Adult and Pediatric Patients ≥ 12 Years of Age and Weighing ≥ 30 kg Who Are HSCT Recipients or Adult and Pediatric Patients ≥ 12 Years of Age and Weighing ≥ 40 kg Who Are Kidney Transplant Recipients:**
  - HSCT: The recommended dose is 480 mg once daily (QD) through Day 100. In patients at risk for late CMV infection and disease, Prevymis may be continued through Day 200.
  - Kidney Transplant: The recommended dose is 480 mg QD through Day 200 post-transplant.

- **Pediatric Patients 6 Months to < 12 Years of Age or ≥ 12 Years of Age and Weighing < 30 kg Who Are HSCT Recipients:** The dose is weight based and administered QD through Day 100. In patients at risk for late CMV infection and disease, Prevymis may be continued through Day 200. Table 1 below provides the recommend dosing of Prevymis.

**Table 1. Recommended Daily Dose in Pediatric HSCT Recipients 6 Months to < 12 Years of Age and Weighing < 30 kg.**

| Body Weight (kg) | Daily Oral Dose | Tablets | Oral Pellets |
|---|---|---|---|
| ≥ 30 kg | 480 mg | One 480 mg tablet | Four 120 mg packets |
| 15 kg to < 30 kg | 240 mg | One 240 mg tablet | Two 120 mg packets |
| 7.5 kg to < 15 kg | 120 mg | Not Recommended | One 120mg packet |
| 6 kg to < 7.5 kg | 80 mg | Not Recommended | Four 20 mg packets |

- The dose of Prevymis should be adjusted based on the patient's weight when co-administered with cyclosporine.

## Availability

Prevymis tablets are available in the following strengths: 240 mg and 480 mg.[1] The tablets are packaged into a carton containing four dose packs, each containing a 7-count blister card for a total of 28 tablets, or into a carton containing two unit-dose 7-count blister cards for a total of 14 tablets. Prevymis tablets should be stored in the original package until use. There are oral pellets approved by the FDA; however, they are not commercially available and not addressed in this policy.

## POLICY STATEMENT

This Drug Quantity Management program has been developed to prevent stockpiling and waste and to address potential order entry error of Prevymis. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration.

## Drug Quantity Limits

| Product | Strength and Form | Retail or Home Delivery Maximum Quantity* |
|---|---|---|
| Prevymis™ (letermovir tablets) | 240 mg tablets | 112 tablets per 365 days<br>30 tablets per Rx |
| | 480 mg tablets | 112 tablets per 365 days<br>30 tablets per Rx |

* Limits may be rounded up to accommodate packaging.

**Infectious Disease – Prevymis Drug Quantity Management Policy – Per Days product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.**

## CRITERIA

**1.** If the medication is being requested for the prophylaxis of cytomegalovirus in a high-risk hematopoietic stem cell transplant patient, approve for the requested quantity, not to exceed a total of 224 tablets per 365 days at retail or home delivery.
Note: Override quantity is rounded up to accommodate packaging.

**2.** If the medication is being requested for the prophylaxis of cytomegalovirus in a high-risk kidney transplant patient, approve for the requested quantity, not to exceed a total of 224 tablets per 365 days at retail or home delivery.
Note: Override quantity is rounded up to accommodate packaging.

## REFERENCES


1. Prevymis® capsules [prescribing information]. Whitehouse Station, NJ: Merck Sharpe & Dohme; August 2024.
2. Marty FM, Ljungman RF, Cemaly J, et al. Letermovir prophylaxis for cytomegalovirus in hematopoietic-cell transplantation. *N Engl J Med.* 2017;377:2433-44.


## HISTORY

| Type of Revision | Summary of Changes | Review Date |
|---|---|---|
| Early Annual Revision | Override criteria updated to approve the requested quantity, not to exceed a total of 224 tablets per 365 days at retail or home delivery if the medication is being requested for the prophylaxis of cytomegalovirus in a high-risk kidney transplant patient.<br><br>Existing criteria approving the requested quantity if the medication is being requested for the prophylaxis of cytomegalovirus in a high-risk hematopoietic stem cell transplant patient was updated to approve the requested quantity, not to exceed a total of 224 tablets. | 09/27/2023 |
| Annual Revision | No criteria changes. | 10/23/2024 |