DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

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

REVIEW DATE: 09/27/2023

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. 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 CMV-seropositive recipients [R+] of an allogeneic **hematopoietic stem cell transplant** (HSCT).
- **CMV prophylaxis** of disease in adult **kidney transplant recipients** at high risk (donor CMV seropositive/recipient CMV seronegative [D+/R-].

Dosing

The recommended dose of Prevymis tablets is 480 mg once daily (QD).[1] In HSCT, Prevymis is initiated between Day 0 and Day 28 post-transplantation (before or after engraftment) and continued through Day 100 post-transplantation.[1,2] In kidney transplant, Prevymis is initiated between Day 0 and Day 7 post-transplantation and continued through Day 200. The dose of Prevymis should be adjusted to 240 mg QD when co-administered with cyclosporine.

Off-Label Use

In retrospective analyses, Prevymis has been found efficacious for prophylaxis of CMV in high-risk HSCT (e.g., patients with graft versus host disease). For this

indication, Prevymis dosing was extended beyond 100 days.[3,4] Prevymis was also efficacious for secondary prophylaxis of CMV in HSCT patients; the median duration of secondary prophylaxis was 125 days.

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.

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 30 tablets per Rx
	480 mg tablets	112 tablets per 365 days 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: Exception 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: Exception quantity is rounded up to accommodate packaging.

REFERENCES

1. Prevymis® capsules [prescribing information]. Whitehouse Station, NJ: Merck Sharpe & Dohme; August 2023.
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.
3. Bansal R, Gordillo CA, Abramova R, et al. Extended letermovir administration, beyond day 100, is effective for CMV prophylaxis in patients with graft versus host disease. *Transpl Infect Dis.* 2021;e123487.
4. Lin A, Maloy M, Su Y, et al. Letermovir for primary and secondary cytomegalovirus prevention in allogeneic hematopoietic cell transplant recipients: Real-world experienced. *Transpl Infect Dis.* 2019;21(6):e133187.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	Policy was updated to reflect the existing quantity limits when a product is obtained via home delivery. No criteria changes.	05/04/2023
Early Annual Revision	Exception 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. 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

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