DRUG QUANTITY MANAGEMENT POLICY – PER RX AND PER DAYS

POLICY: Infectious Disease – Prevymis Drug Quantity Management Policy – Per Rx and Per Days
- Prevymis® (letermovir tablets and oral pellets – Merck)

REVIEW DATE: 10/29/2025

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 WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. 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 of age 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

HSCT Dosing

- Adult and pediatric patients ≥ 12 years of age who weigh ≥ 30 kg: The recommended dose is 480 mg once daily (QD) through Day 100.[1] This dose can be achieved using one 480 mg tablet QD, two 240 mg tablets QD, or four 120 mg packets of oral pellets, if the patient cannot swallow tablets. In patients at risk for late CMV infection and disease, Prevymis may be continued through Day 200. When co-administered with cyclosporine, the dose of Prevymis should be decreased to 240 mg QD.
- Pediatric patients 6 months to < 12 years of age or who weigh < 30 kg: 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 recommended dosing. If co-admnistered with cyclosporine, the dose of Prevymis should be adjusted as outlined in Table 2.

Table 1. Recommended Dose of Prevymis in 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 or Two 240 mg tablets	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

Table 2. Recommended Dose of Prevymis when Co-administered with Cyclosporine in HSCT Recipients 6 Months to < 12 Years of Age and Weighing < 30 kg.[1]

Body Weight (kg)	Daily Oral Dose	Tablets	Oral Pellets
≥ 30 kg	240 mg	One 240 mg tablet	Two 120 mg packets
15 kg to < 30 kg	120 mg	Not recommended	One 120 mg packets
7.5 kg to < 15 kg	60 mg	Not Recommended	Three 20mg packets
6 kg to < 7.5 kg	40 mg	Not Recommended	Two 20 mg packets

Kidney Transplant Dosing

The recommended dose is 480 mg QD through Day 200 post-transplant.[1] This dose can be achieved using one 480 mg tablet QD, two 240 mg tablets QD, or four 120 mg packets of oral pellets, if the patient cannot swallow tablets. When co-administered with cyclosporine, the dose of Prevymis should be decreased to 240 mg QD.

There are some data to support the use of Prevymis beyond 200 days post-transplant, particularly in high-risk patients.[2]

Availability

Prevymis is available as oral tablets and pellets.[1] Prevymis tablets are available in 240 mg and 480 mg strengths that 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. Prevymis oral pellets are available in 20 mg and 120 mg packets supplied in cartons of 30 packets each.

Additional Information

The quantity limits below allow for 200 days of therapy with Prevymis. Overrides are provided for longer term treatment. For the 480 mg tablets, the base quantity limits allow for 224 tablets per 365 days, which is a quantity sufficient for 480 mg QD dosing for 200 days, rounded up to the nearest package size. For the 240 mg tablets, the base quantity limits allow for 420 tablets per 365 days, which is a quantity sufficient for 480 mg QD dosing for 200 days, rounded up to the nearest package size. This is in line with product labeling which states that the 480 mg dose can be achieved using either one 480 mg tablet QD, two 240 mg tablets QD, or four 120 mg packets of oral pellets. For the 20 mg oral pellet packets, the base quantity limits allow for 810 packets per 365 days, which is a quantity sufficient for 80 mg (four 20 mg packets) QD dosing for 200 days, rounded up to the nearest package size. For the 120 mg oral pellet packets, the base quantity limits allow for 810 packets per 365 days, which is a quantity sufficient for 480 mg (four 120 mg packets) QD dosing for 200 days, rounded up to the nearest package size. Again, this is in line with product labeling which states that the 480 mg dose can be achieved using either one 480 mg tablet QD, two 240 mg tablets QD, or four 120 mg packets of oral pellets.

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 Maximum Quantity*	Home Delivery Maximum Quantity*
Prevymis™ (letermovir tablets and oral pellets)	240 mg tablets	420 tablets per 365 days	
		56 tablets per Rx	
	480 mg tablets	224 tablets per 365 days	
		28 tablets per Rx	
	20 mg oral pellet packets	810 packets per 365 days	
		120 packets per Rx	
	120 mg oral pellet packets	810 packets per 365 days	
		120 packets per Rx	

* Limits are rounded up to accommodate packaging.

EXCEPTIONS TO THE QUANTITY LIMITS LISTED ABOVE ARE COVERED AS MEDICALLY NECESSARY WHEN THE FOLLOWING CRITERIA ARE MET. ANY OTHER EXCEPTION IS CONSIDERED NOT MEDICALLY NECESSARY.

CRITERIA

Prevymis tablets and oral pellets (all strengths) "Per Rx" Limit
No overrides recommended.

Prevymis 240 mg tablets "Per Days" Limit

1. If the medication is being requested for the prophylaxis of cytomegalovirus in a high-risk hematopoietic stem cell transplant patient, approve 756 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 756 tablets per 365 days at retail or home delivery.
Note: Override quantity is rounded up to accommodate packaging.

Prevymis 480 mg tablets "Per Days" Limit

1. If the medication is being requested for the prophylaxis of cytomegalovirus in a high-risk hematopoietic stem cell transplant patient, approve 392 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 392 tablets per 365 days at retail or home delivery.
Note: Override quantity is rounded up to accommodate packaging.

Prevymis 20 mg oral pellet packets and 120 mg oral pellet packets "Per Days" Limit

1. If the medication is being requested for the prophylaxis of cytomegalovirus in a high-risk hematopoietic stem cell transplant patient, approve 1,470 packets 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 1,470 packets per 365 days at retail or home delivery.
Note: Override quantity is rounded up to accommodate packaging.

REFERENCES

1. Prevymis® capsules [prescribing information]. Rahway, NJ: Merck; January 2025.
2. Vyas A, Raval AD, Kamat S, et al. Real-world outcomes associated with letermovir use for cytomegalovirus primary prophylaxis in allogeneic hematopoietic cell transplant recipients: a systematic review and meta analysis of observational studies. *Open Forum Infect Dis*. 2022;10(1):ofac687.

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. 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
Annual Revision	Policy Name was updated to "Infectious Disease – Prevymis DQM Policy – Per Rx and Per Days". Previously, the Policy Name was "Infectious Disease – Prevymis DQM Policy – Per Days". **Prevymis 240 mg tablets:** The "Per Rx" quantity limits were updated to 56 tablets per dispensing at retail or home delivery. Previously, the "Per Rx" quantity limits were 30 tablets per dispensing at retail or home delivery. No clinical overrides apply to the "Per Rx" limits. The "Per Days" quantity limits were updated to 420 tablets per 365 days at retail or home delivery. Previously, the "Per Days" quantity limits were 112 tablets per 365 days at retail or home delivery. Overrides to these "Per Days" limits were updated to approve 756 tablets per 365 days at retail or home delivery if the medication is being requested for the prophylaxis of cytomegalovirus in a high-risk hematopoietic stem cell transplant patient or a high-risk kidney transplant patient. Previously, these overrides approved the requested quantity, not to exceed a total of 224 tablets per 365 days. **Prevymis 480 mg tablets:** The "Per Rx" quantity limits were updated to 28 tablets per dispensing at retail or home delivery. Previously, these limits were 30 tablets per dispensing. No clinical overrides apply to the "Per Rx" limits. The "Per Days" quantity limits were updated to 224 tablets per 365 days at retail or home delivery. Previously, the "Per Days" quantity limits were 112 tablets per 365 days at retail or home delivery. Overrides to these "Per Days" limits were updated to approve 392 tablets per 365 days at retail or home delivery if the medication is being requested for the prophylaxis of cytomegalovirus in a high-risk hematopoietic stem cell transplant patient or a high-risk kidney transplant patient. Previously, these overrides approved the requested quantity, not to exceed a total of 224 tablets per 365 days. **Prevymis 20 mg and 120 mg oral pellet packets:** New "Per Rx" quantity limits were added of 120 packets per dispensing at retail or home delivery. No clinical overrides apply to the "Per Rx" limits. New "Per Days" quantity limits were added of 810 packets per 365 days at retail or home delivery. New "Per Days" overrides were added to approve 1,470 packets per 365 days at retail or home delivery if the medication is being requested for the prophylaxis of cytomegalovirus in a high-risk hematopoietic stem cell transplant patient or a high-risk kidney transplant patient.	10/29/2025