Drug Coverage Policy

Effective Date.....4/01/2024
Coverage Policy Number.....IP0426
Policy Title.....Prevymis for Individual and Family Plans

Infectious Disease – Prevymis for Individual and Family Plans

- Prevymis™ (letermovir tablets – Merck Sharp & Dohme)

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.

Medical Necessity Criteria

Prevymis is considered medically necessary when the following is met:

1. **Prophylaxis of Cytomegalovirus (CMV) Infection.** Individual meets **ONE** of the following criteria:

A. Is a CMV-seropositive [R+] adult recipient of an allogeneic hematopoietic stem cell transplant (HSCT).
B. Is an adult kidney transplant recipient at high risk (donor CMV seropositive/recipient CMV seronegative [D+/R-]

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Reauthorization Criteria

Not applicable for continuation beyond initial approval duration.

Authorization Duration

CMV Prophylaxis in Hematopoietic Stem Cell Transplant (HSCT) Recipients: up to 14 weeks or 100 days post-HSCT

CMV Prophylaxis in Kidney Transplant Recipients: up to 28 weeks or 200 days post-transplant

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven.

Background

OVERVIEW
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.

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.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	• Updated title of policy • Added new criterion for expanded use in adult kidney transplant recipient at high risk (donor CMV seropositive/recipient CMV seronegative [D+/R-])	4/1/2024

The policy effective date is in force until updated or retired.