Pharmacy Medical Necessity Guidelines: Prevymis™ (letermovir) tablet

Effective: January 1, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

Prevymis™ is a cytomegalovirus (CMV) DNA terminase complex inhibitor indicated for prophylaxis of CMV infection and disease in adult and pediatric patients 6 months of age and older and weighing at least 6 kg who are CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT). It is also indicated for prophylaxis of CMV disease in adult and pediatric patients 12 years of age and older and weighing at least 40 kg who are kidney transplant recipients at high risk (Donor CMV seropositive/Recipient CMV seronegative [D+/R-]).

Prevymis™ is available as tablets for oral administration and solution for intravenous use. Prevymis™ injection should be used only in patients unable to take oral therapy. Patients should be switched to oral Prevymis ™ as soon as they are able to take oral medications.

COVERAGE GUIDELINES

The plan may authorize coverage of Prevymis™ (letermovir) tablet for Members, when the following criteria are met:

Prophylaxis of CMV infection and disease and CMV-seropositive recipients of an allogeneic hematopoietic stem cell transplant (HSCT)

1. Documentation that patient has received, or is scheduled to receive, an allogeneic hematopoietic stem cell transplant (HSCT) (*Note: Date of HSCT must be submitted on the request)*

AND

2. Patient is at high risk of CMV infection (e.g. CMV-seropositive recipients, seronegative recipients who receive a graft from seropositive donor)

Prophylaxis of CMV disease in adult and pediatric patients 12 years of age and older and weighing at least 40 kg who are kidney transplant recipients at high risk

1. Documentation the patient has received, or is scheduled to receive, a kidney transplant *(Note: Date of kidney transplant must be submitted on requested)*

AND

2. Patient is at high risk of CMV infection (Donor CMV seropositive/Recipient CMV seronegative [D+/R-])

LIMITATIONS

1. Coverage of Prevymis™ (letermovir) is limited to maximum of:
    a. **HSCT:** 100 days post-transplant. Members at risk for late CMV infection and disease may continue therapy through 200 days post-HSCT (provider documentation of risk and medical necessity required)
    b. **Kidney transplant:** 200 days post-transplant

CODES

None

REFERENCES

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9. National Comprehensive Cancer Network. Referenced from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Prevention and Treatment of Cancer-Related Infections, V.1.2018. © National Comprehensive Cancer Network, Inc. 2017. All rights reserved. Accessed January 2018. To view the most recent and complete version of the guideline, go online to NCCN.org. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, NCCN GUIDELINES®, and all other NCCN Content are trademarks owned by the National Comprehensive Cancer Network, Inc.
10. Prevymis (letermovir) [prescribing information]. Whitehouse Station, NJ: Merck & Co., Inc.; January 2025.
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APPROVAL HISTORY

September 13, 2022: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. May 9, 2023: No changes.
2. November 14, 2023: Effective December 1, 2023, updated MNG to include the supplemental indication of prophylaxis of CMV disease in adult kidney transplant recipients at high risk (D+/R-). Updated length of approval for HSCT to up to 200 days for members at risk of CMV infection and disease. Updated limitations section to remove statement that the plan will not cover Prevymis for any indication beyond what is included in the Pharmacy Coverage Guidelines, as it is redundant. Updated Pharmacy Utilization management fax number.
3. November 12, 2024: Effective November 12, 2024: Added additional FDA approved indication to overview: for prophylaxis of cytomegalovirus (CMV) infection and disease in pediatric patients 6 months of age and older and weighing at least 6 kg who are CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT). Added additional FDA approved indication to overview and coverage criteria: indicated for prophylaxis of CMV disease in pediatric patients 12 years of age and older and weighing at least 40 kg who are kidney transplant recipients at high risk (Donor CMV seropositive/Recipient CMV seronegative [D+/R-]
4. December 2025 E-Vote: no changes (1/1/26)

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

Provider Services