



PHARMACY POLICY STATEMENT TRICARE

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|------------------|------------------------------|
| DRUG NAME | Prevymis (letermovir) |
| BENEFIT TYPE | Pharmacy or Medical |
| STATUS | Prior Authorization Required |

Prevymis, approved in 2017, is indicated for the prophylaxis of cytomegalovirus (CMV) infection and disease in adult and pediatric patients 6 months of age and older weighing at least 6 kg who are CMV-seropositive recipients of an allogeneic hematopoietic stem cell transplant (HSCT) and 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). Prevymis works by inhibiting the CMV DNA terminase complex which is required for viral DNA processing and packaging.

Prevymis (letermovir) will be considered for coverage when the following criteria are met:

HSCT CMV Prophylaxis

For initial authorization:

1. Member is at least 6 months of age and 6 kg; AND
2. Medication must be prescribed by or in consultation with an infectious disease specialist, hematologist, or transplant specialist; AND
3. Member is the recipient of an allogeneic stem cell transplant; AND
4. Member must be CMV-seropositive; AND
5. Provider attests Prevymis will be initiated within 28 days post-transplant; AND
6. Provider attests that member is **NOT** currently taking the following:
 - a) Pimozide;
 - b) Ergot alkaloids (ergotamine, dihydroergotamine);
 - c) Pitavastatin or simvastatin with cyclosporine; AND
7. For the IV formulation: documentation must be submitted that the member cannot tolerate or has a contraindication to the oral tablet.
8. **Dosage allowed/Quantity limit:** Quantity limit: 28 tablet/vials per 28 days or 120 packets per 30 days.
 - a) 6 months to less than 12 years of age or 12 years of age and older and weighing less than 30 kg: dosing based on weight (see below) administered once daily orally or as an IV infusion over 1 hour through 100 days post-HSCT.



| Body Weight | Daily Oral Dose | Tablets | Oral Pellets |
|---------------------------|-----------------|---|-------------------------------------|
| 30 kg and above | 480 mg | One 480 mg tablet or Two 240 mg tablets | Four 120 mg packets of oral pellets |
| 15 kg to less than 30 kg | 240 mg | One 240 mg tablet | Two 120 mg packets of oral pellets |
| 7.5 kg to less than 15 kg | 120 mg | Not recommended | One 120 mg packet of oral pellets |
| 6 kg to less than 7.5 kg | 80 mg | Not recommended | Four 20 mg packets of oral pellets |

| Body Weight | Daily IV* Dose |
|---------------------------|----------------|
| 30 kg and above | 480 mg |
| 15 kg to less than 30 kg | 120 mg |
| 7.5 kg to less than 15 kg | 60 mg |
| 6 kg to less than 7.5 kg | 40 mg |

b) Adult and pediatric patients 12 years of age and older and weighing at least 30 kg: administer 480 mg once daily orally or as an intravenous (IV) infusion over 1 hour through 100 days post-transplant.

NOTE: In patients at risk for late CMV infection and disease, Prevymis may be continued through 200 days post-HSCT.

If all the above requirements are met, the medication will be approved for 100 days.

For reauthorization:

1. Medication will not be reauthorized.

Kidney Transplant CMV Prophylaxis

For initial authorization:

1. Member is at least 12 years of age and 40 kg; AND
2. Medication must be prescribed by or in consultation with an infectious disease specialist, hematologist, or transplant specialist; AND
3. Member is the recipient of a kidney transplant; AND
4. Member must be at high risk (donor CMV-seropositive and recipient CMV seronegative); AND
5. Provider attests Prevymis will be initiated within 7 days post-transplant; AND
6. Member is unable to use valganciclovir; AND
7. Provider attests that member is **NOT** currently taking the following:
 - a. Pimozide;
 - b. Ergot alkaloids (ergotamine, dihydroergotamine);
 - c. Pitavastatin or simvastatin with cyclosporine; AND
8. For the IV formulation: documentation must be submitted that the member cannot tolerate or has a contraindication to the oral tablet.
9. **Dosage allowed/Quantity limit:** administer 480 mg once daily orally or as an intravenous (IV) infusion over 1 hour through 200 days post-transplant. Quantity limit: 28 tablet/vials per 28 days or 120 packets per 30 days.

If all the above requirements are met, the medication will be approved for 200 days.



For **reauthorization**:

1. Medication will not be reauthorized.

TRICARE Prime® Demo by CareSource Military & Veterans™ considers Prevymis (letermovir) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

| DATE | ACTION/DESCRIPTION |
|------------|--|
| 02/14/2022 | New policy for Prevymis created. |
| 07/05/2023 | Added kidney transplant indication; added quantity limit; added references; added medical benefit option |
| 02/05/2025 | Updated references; expanded age limit and added weight requirement per PI for both diagnoses; added pediatric dosing; removed note about coadministration with cyclosporine; added provider attestation for medications member is not taking; added packets to quantity limit; added note for HSCT about continuing through 200 days for patients at risk for late CMV. |

References:

1. Prevymis [package insert]. County Carlow, Ireland: Merck Sharp & Dohme Corporation; 2024.
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3. Kropoet D, McCormick D, Erb-Zohar K, et al. Pharmacokinetics and safety of the anti-human cytomegalovirus drug letermovir in subjects with hepatic impairment. *Br J Clin Pharmacol.* 2017a;83(12):2678-2686.
4. Malagola M, Radici V, Farina M, et al. Correction: CMV prophylaxis with letermovir significantly improves graft and relapse free survival following allogeneic stem cell transplantation. *Bone Marrow Transplant.* 2024;59(2):293. doi:10.1038/s41409-023-02158-2
5. Kotton CN, Kumar D, Caliendo AM, et al. The Third International Consensus Guidelines on the Management of Cytomegalovirus in Solid-organ Transplantation. *Transplantation.* 2018; 102:900.
6. Razonable RR, Humar A. Cytomegalovirus in solid organ transplant recipients-Guidelines of the American Society of Transplantation Infectious Diseases Community of Practice. *Clin Transplant.* 2019;33(9):e13512. doi:10.1111/ctr.13512
7. Limaye AP, Budde K, Humar A, et al. Letermovir vs Valganciclovir for Prophylaxis of Cytomegalovirus in High-Risk Kidney Transplant Recipients: A Randomized Clinical Trial. *JAMA.* 2023;330(1):33-42. doi:10.1001/jama.2023.9106

Effective date: 01/01/2026

Revised date: 02/05/2025