CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Indiana Medicaid

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

Prevymis is a terminase complex inhibitor initially approved by the FDA in 2017. It is indicated for the prophylaxis of CMV infection and disease in adult CMV-seropositive recipients of an allogeneic hematopoietic stem cell transplant (HSCT) and adult 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 18 years of age; 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. Prescriber attests Prevymis will be initiated within 28 days post-transplant; AND
6. Member is not currently taking the following:
   a) Pimozide
   b) Ergot Akaloids (ergotamine, dihydroergotamine)
   c) Pitavastatin or Simvastatin with Cyclosporine
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:** Administer 480 mg once daily orally or as an intravenous (IV) infusion over 1 hour through 100 days post-transplant. Quantity Limit: 28 tablets or vials per 28 days. NOTE: If PREVYMIS is given with cyclosporine, the dosage of Prevymis should be decreased to 240 mg once daily.

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 18 years of age; 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. Prescriber attests Prevymis will be initiated within 7 days post-transplant; AND
6. Member is unable to use valganciclovir; AND
7. Member is not currently taking the following:
   a. Pimozide
   b. Ergot Akaloids (ergotamine, dihydroergotamine)
   c. Pitavastatin or Simvastatin with Cyclosporine
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 tablets or vials per 28 days.

NOTE: If PREVYMIS is given with cyclosporine, the dosage of Prevymis should be decreased to 240 mg once daily.

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

For **reauthorization**:

1. Medication will not be reauthorized.

CareSource 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

References:

1. Prevymis [package insert]. County Carlow, Ireland: Merck Sharp & Dohme Corporation; June 2023.
2. Marty FM, Ljungman P, Chemaly RF, et al. Letermovir prophylaxis for cytomegalovirus in hematopoietic-cell transplantation. *N Engl J Med*. 2017; 377(25):2433-44.
3. Kropeit 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. 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.
5. 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
6. 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

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