CareSource Rx Innovations

PHARMACY POLICY STATEMENT
Georgia Medicaid

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 akaloids (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 akaloids (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.

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

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. 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. 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

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