

Prevymis (letermovir)

Meets Primary Coverage Criteria Or Is Covered For Contracts Without Primary Coverage Criteria

Letermovir meets member benefit certificate primary coverage criteria that there be scientific evidence of effectiveness in improving health outcomes for the following indications (FDA Prevymis, 2017):

1. Prophylaxis of cytomegalovirus (CMV) infection and disease in recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT) when the following criteria are met:
 - a. Individual is 6 months of age and older (Prevymis, 2023); **AND**
 - b. Individual weighs at least 6 kg; **AND**
 - c. Individual is CMV-seropositive(Prevymis, 2023); **AND**
 - d. Individual has tried and had an inadequate response to, intolerance, or contraindication to valganciclovir and ganciclovir for prophylaxis; **AND**
 - e. Letermovir is started between day 0 and day 28 post HSCT (before or after engraftment) and continue through day 100 post HSCT. (Prevymis, 2023); **AND**
 - f. Individual will not be receiving in combination with other antivirals for CMV (e.g., ganciclovir, valganciclovir, foscarnet, etc.). Letermovir may be given with antivirals for prophylaxis of varicella zoster virus (VZV) or herpes simplex virus (HSV) (e.g., acyclovir or valacyclovir); **AND**
 - g. Individual will not be receiving in combination with pimozide or ergot alkaloids (Prevymis, 2023); **AND**
 - h. Individual will not be receiving in combination with cyclosporine co-administered with pravastatin or simvastatin (Prevymis, 2023); **AND**
 - i. Must be dosed in accordance with the FDA label.

2. Prophylaxis of CMV disease in kidney transplant recipients when the following criteria are met:
 - a. Individual is 12 years of age and older (Prevymis, 2023); **AND**
 - b. Individual weighs at least 40kg; **AND**
 - c. Individual is at high risk [Donor CMV seropositive/Recipient CMV seronegative (D+/R-)] (Prevymis, 2023); **AND**
 - d. Individual has tried and had an inadequate response to, intolerance, or contraindication to valganciclovir and ganciclovir for prophylaxis; **AND**

- e. Letermovir is started between Day 0 and Day 7 post-transplant and continue through Day 200 post-transplant (Prevymis, 2023); **AND**
- f. Individual will not be receiving in combination with other antivirals for CMV (e.g., ganciclovir, valganciclovir, foscarnet, etc.) Letermovir may be given with antivirals for prophylaxis of varicella zoster virus (VZV) or herpes simplex virus (HSV) (e.g., acyclovir or valacyclovir); **AND**
- g. Individual will not be receiving in combination with pimozide or ergot alkaloids (Prevymis, 2023); **AND**
- h. Individual will not be receiving in combination with cyclosporine co-administered with pravastatin or simvastatin (Prevymis, 2023); **AND**
- i. Must be dosed in accordance with the FDA label.

Dosing and Administration

Dosing per FDA Guidelines

HSCT:

The recommended dosage of letermovir is 480 mg once daily through 100 days HSCT. In individuals at risk for late CMV infection and disease, letermovir may be continued through 200 days post-HSCT.

Kidney transplant:

The recommended dosage of letermovir is 480 mg administered once daily through 200 days post-transplant.

Dosage Adjustment:

If letermovir is co-administered with cyclosporine, the dosage of letermovir should be decreased to 240 mg daily.

Drug	Daily Limit
Prevymis 480 mg (letermovir tablet)	1 tablet
Prevymis 240 mg (letermovir tablet)	2 tablets
Prevymis (letermovir oral pellets)	4 packets

Does Not Meet Primary Coverage Criteria Or Is Investigational For Contracts Without Primary Coverage Criteria

The use of Letemovir for any indication or circumstance not described above does not meet member benefit certificate primary coverage criteria that there be scientific evidence of effectiveness in improving health outcomes.

For members with contracts without primary coverage criteria, the use of Letemovir for any indication or circumstance not described above is considered **investigational**. **Investigational** services are specific contract exclusions in most member benefit certificates of coverage.