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5.01.043

Section:	Prescription Drugs	**Effective Date:**	January 1, 2024
Subsection:	Anti-Infective Agents	**Original Policy Date:**	December 1, 2017
Subject:	Prevymis	**Page:**	1 of 4

Last Review Date: December 8, 2023

Prevymis

Description

Prevymis (letermovir)

Background
Prevymis (letermovir) is a once-daily tablet for oral use and injection for intravenous infusion. Prevymis is an antiviral drug used for the prevention of cytomegalovirus (CMV) infection and disease in adults. CMV is a common and potentially serious viral infection (1).

Regulatory Status
FDA-approved indications: Prevymis is a CMV DNA terminase complex inhibitor indicated for: (1)

- Prophylaxis of cytomegalovirus (CMV) infection and disease in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT).
- Prophylaxis of CMV disease in adult kidney transplant recipients at high risk (Donor CMV seropositive/Recipient CMV seronegative [D+/R-]).

Prevymis is contraindicated in patients receiving pimozide or ergot alkaloids. Prevymis is also contraindicated with pitavastatin and simvastatin when co-administered with cyclosporine (1).

Prevymis is not recommended for patients with severe (Child-Pugh Class C) hepatic impairment (1).

Safety and efficacy of Prevymis in patients less than 18 years of age have not been established (1).

Related policies
Livtencity, Valcyte

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Prevymis may be considered **medically necessary** if the conditions indicated below are met.

Prevymis may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Prevention (prophylaxis) of cytomegalovirus (CMV) infection and disease
    a. Post hematopoietic stem cell transplant (HSCT) within the last 28 days
    b. CMV seropositive recipient [R+]
2. Prevention (prophylaxis) of cytomegalovirus (CMV) infection and disease
    a. Post kidney transplant within the last 7 days
    b. CMV seropositive donor/CMV seronegative recipient (D+/R-)

AND ALL of the following for **ALL** indications:
    a. **NO** severe (Child-Pugh Class C) hepatic impairment
    b. Prescriber agrees to monitor for CMV reactivation

Policy Guidelines

Pre - PA Allowance
None

Prior - Approval Limits

Quantity

Strength	Quantity
240 mg tablet	224 tablets per 200 days **OR**
480 mg tablet	
240 mg (12 mL vial)	200 vials per 200 days
480 mg (24 mL vial)	

Rationale

Summary

Prevymis (letermovir) is a once-daily tablet for oral use and injection for intravenous infusion. Prevymis is used for the prevention of cytomegalovirus (CMV) infection and disease in adults. Prevymis is contraindicated in patients receiving pimozide or ergot alkaloids. Prevymis is also contraindicated with pitavastatin and simvastatin when co-administered with cyclosporine. Prevymis is not recommended for patients with severe (Child-Pugh Class C) hepatic impairment. Safety and efficacy of Prevymis in patients less than 18 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Prevymis while maintaining optimal therapeutic outcomes.

References

1. Prevymis [package insert]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp.; August 2023.

Policy History

Date	Action
December 2017	New Addition
March 2018	Annual review
December 2019	Annual review and reference update
December 2020	Annual review and reference update
September 2021	Annual review and reference update
March 2022	Annual editorial review
June 2023	Annual review and reference update. Changed policy number to 5.01.043
July 2023	Per PI update, added new indication of CMV prophylaxis in kidney transplant recipients

August 2023	Per PI update, revised quantity chart to allow for 200 days of therapy for either HSCT or kidney transplant
December 2023	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 8, 2023 and is effective on January 1, 2024.