Prevymis

Description

Prevymis (letermovir)

Background
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 to treat adults who are CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT). CMV is a common and potentially serious viral infection in allogeneic HSCT recipients. CMV-seropositive patients who undergo an HSCT are at high risk for CMV reactivation (1).

Regulatory Status
FDA-approved indications: is a CMV DNA terminase complex inhibitor indicated for prophylaxis of cytomegalovirus (CMV) infection and disease in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT) (1).

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 below 18 years of age have not been established (1).

Related policies
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** for patients 18 years and older for the prevention (prophylaxis) of cytomegalovirus (CMV) infection and disease in patients and if the conditions indicated below are met.

Prevymis is considered **investigational** in patients less than 18 years of age and for all other indications.

**Prior-Approval Requirements**

**Age**

18 years of age or older

**Diagnosis**

Patient must have 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 sero-positive recipient [R+]
   c. **NO** severe (Child-Pugh Class C) hepatic impairment
   d. Prescriber agrees to monitor for CMV reactivation

**Policy Guidelines**

**Pre - PA Allowance**

None

**Prior - Approval Limits**

**Quantity**

<table>
<thead>
<tr>
<th>Tablets</th>
<th>112 tablets per 100 days OR</th>
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<tr>
<td>240 mg</td>
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<tr>
<td>480 mg</td>
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**Infusion**

- 240 mg (12 mL vial) 100 vials per 100 days **OR**
- 480 mg (24 mL vial) 100 vials per 100 days

**Duration**

100 days

**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 to treat adults with CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT). 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 below 18 years of age have not been established.

**References**


**Policy History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>December 2017</td>
<td>New Addition</td>
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<tr>
<td>March 2018</td>
<td>Annual review</td>
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<tr>
<td>December 2019</td>
<td>Annual review and reference update</td>
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**Keywords**

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 6, 2019 and is effective on January 1, 2020.