Description
Letermovir (Prevymis™) is an orally administered antiviral agent that inhibits cytomegalovirus (CMV) deoxyribonucleic acid (DNA) terminase complex which helps prevent CMV infection in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT).

Length of Authorization
- Initial: up to 100 days post-transplant
- Renewal: no renewal

Quantity limits

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Dosage Form</th>
<th>Indication</th>
<th>Quantity Limit</th>
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<tbody>
<tr>
<td>letermovir</td>
<td>240 mg tablet</td>
<td>Prophylaxis for CMV Infection</td>
<td>30 tablets/30 days</td>
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<tr>
<td>(Prevymis)</td>
<td>480 mg tablet</td>
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Initial Evaluation

I. Letermovir (Prevymis) may be considered medically necessary when the following criteria below are met:
   A. Member is 18 years of age or older; AND
   B. Medication is prescribed by, or in consultation with, an oncologist, hematologist, infectious disease, or transplant specialist; AND
   C. Member will be using letermovir (Prevymis) for the prevention of CMV infection or disease; AND
   D. Member is cytomegalovirus (CMV)-seropositive; AND
   E. Member is an allogeneic hematopoietic stem cell transplant (HSCT) recipient with a high risk of CMV reactivation; AND
   F. Documentation of transplant date has been recorded in chart notes; AND
   G. Treatment with valacyclovir (Valtrex), or ganciclovir (Cytobene) has been ineffective, contraindicated, or not tolerated; AND
   H. If the request is for letermovir (Prevymis) 240 mg, it will be used in combination with cyclosporine.

II. Letermovir (Prevymis) is considered investigational when used for all other conditions, including but not limited to:
   A. Prevention of CMV infection or disease in all other settings EXCEPT HSCT
   B. Treatment for CMV infection or disease
Supporting Evidence

I. Per label, letermovir (Prevymis) has only been FDA-approved in the setting of CMV prophylaxis in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT).

II. Guidelines for HSCT recommend valacyclovir (Valtrex), ganciclovir (Cytobene), foscavir (Foscarnet), or letermovir (Prevymis) for CMV prophylaxis. The guidelines state that foscavir (Foscarnet) and letermovir (Prevymis) have a more favorable side effect profile; however, do not recommend preference of one agent over another in regards to efficacy.

III. The safety and efficacy of letermovir (Prevymis) was studied in a multicenter, double-blind, placebo-controlled, Phase 3 trial in adult CMV-seropositive recipients [R+] of those who have received an allogeneic hematopoietic stem cell transplant (HSCT). Of the 325 participants who received letermovir (Prevymis), 38% failed prophylaxis compared to 61% in the placebo arm [95% CI (32.5, 14.6)].

Investigational or Not Medically Necessary Uses

I. There is a lack of strong scientific evidence from randomized controlled trials supporting safety and efficacy for the following indications below:
   A. Prevention of CMV infection or disease in all other settings EXCEPT HSCT
   B. Treatment for CMV infection or disease

References


Policy Implementation/Update:

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<tr>
<th>Date Created</th>
<th>November 2019</th>
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<tr>
<td>Date Effective</td>
<td>December 2019</td>
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<tr>
<td>Last Updated</td>
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Action and Summary of Changes

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