Letermovir (Prevymis™) for Cytomegalovirus Prophylaxis in Hematopoietic Stem Cell Transplant Patients

**POLICY**

Letermovir (Prevymis™) is considered **medically necessary** for the treatment of adult patients for prophylaxis of cytomegalovirus (CMV) infection and disease in CMV seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT) when ALL of the following criteria are met:

A. The patient is 18 years of age or older; **AND**
B. The patient is being managed by or in consultation with a hematologist/oncologist, infectious disease, or transplant specialist; **AND**
C. The patient is a recipient of an allogeneic hematopoietic stem cell transplant (clinical documentation required); **AND**
D. The patient has a confirmed CMV seropositive recipient (R+) (clinical documentation required); **AND**
E. The patient is being treated for the prophylaxis of CMV infection and disease; **AND**
F. The 240mg dose will only be approved in those treated concomitantly with cyclosporine; **AND**
G. The patient has not exceeded 30 days post-transplantation; **AND**
H. If request is for IV Prevymis, must provide medical justification why the patient cannot use oral therapy.

Length of Approval: Through Day 100 post-transplantation.
POLICY GUIDELINES

Prevymis is a drug used to help prevent cytomegalovirus (CMV) infection and disease in adults previously exposed to CMV infection, who have received a stem cell (bone marrow) transplant. Stem cell (bone marrow) transplant is one way of treating some blood cancers. Many transplant recipients are at high risk for CMV infection and disease because of their weakened immune system.

Prevymis is used once a day and may be taken by mouth in the form of a tablet or given intravenously when patient is unable to take it by mouth.

BENEFIT APPLICATION

BLUECARD/NATIONAL ACCOUNT ISSUES

State or federal mandates (eg, Federal Employee Program) may dictate that certain U.S. Food and Drug Administration–approved devices, drugs, or biologics may not be considered investigational, and thus these devices may be assessed only by their medical necessity.

RATIONALE

In the pivotal phase 3 clinical trial supporting approval, significantly fewer patients in the letermovir group (38%, 122 of 325) compared with the placebo group (61%, 103 of 170) developed clinically significant CMV infection, discontinued treatment, or had missing data through week 24 post-HSCT (treatment difference: –23.5 [95% confidence interval, –32.5 to –14.6; P < 0.0001]), the primary efficacy endpoint.

All-cause mortality in patients receiving letermovir was lower compared with placebo, 12% versus 17%, respectively, at week 24 post-transplant. In this study, the incidence of bone marrow suppression in the letermovir group was comparable to the placebo group. The median time to engraftment was 19 days in the letermovir group and 18 days in the placebo group.

Letermovir is contraindicated in patients receiving pimozide or ergot alkaloids. The concomitant use of letermovir and certain drugs may result in potentially significant drug interactions.

Among the more than 27,000 allogeneic HSCTs performed each year worldwide (including approximately 8,500 transplants in the United States), an estimated 65% to 80% of recipients have been previously exposed to CMV and are therefore at high risk for CMV infection. Without prophylactic measures, many patients undergoing allogeneic HSCT will experience CMV infection, which can cause a range of serious negative health outcomes in this population.

SUPPLEMENTAL INFORMATION

PRACTICE GUIDELINES AND POSITION STATEMENTS

U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS

Not applicable.

MEDICARE NATIONAL COVERAGE

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.
ESSENTIAL HEALTH BENEFITS

The Affordable Care Act (ACA) requires fully insured non-grandfathered individual and small group benefit plans to provide coverage for ten categories of Essential Health Benefits (“EHBs”), whether the benefit plans are offered through an Exchange or not. States can define EHBs for their respective state.

States vary on how they define the term small group. In Idaho, a small group employer is defined as an employer with at least two but no more than fifty eligible employees on the first day of the plan or contract year, the majority of whom are employed in Idaho. Large group employers, whether they are self-funded or fully insured, are not required to offer EHBs, but may voluntarily offer them.

The Affordable Care Act requires any benefit plan offering EHBs to remove all dollar limits for EHBs.

REFERENCES


CODES

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POLICY HISTORY

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<td>Blue Cross of Idaho adopted new policy with literature review through April 27, 2018. Effective date 07/30/2018.</td>
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<td>Replace policy</td>
<td>Blue Cross of Idaho Annual review, no change to policy statements.</td>
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