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Corporate Medical Policy

Letermovir (Prevymis™)

File Name: letermovir_prevymis
Origination: 2/2018
Last CAP Review: 3/2020
Next CAP Review: 3/2021
Last Review: 3/2020

Description of Procedure or Service

Prevymis™ is a cytomegalovirus (CMV) DNA terminase complex inhibitor indicated for prophylaxis of CMV infection and disease in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT).

***Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.

Policy

BCBSNC will provide coverage for Letermovir (Prevymis™) when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Letermovir (Prevymis) is covered

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:

1. The patient is 18 years of age or older; AND
2. The patient is being managed by or in consultation with an hematologist/oncologist, infectious disease, or transplant specialist; AND
3. The patient is a recipient of a allogeneic hematopoietic stem cell transplant (medical record documentation required); AND
4. The patient is a confirmed CMV seropositive recipient (R+) (medical record documentation required); AND
5. The patient is being treated for the prophylaxis of CMV infection and disease; AND
Letermovir (Prevymis™)

6. The 240mg dose will only be approved in those treated concomitantly with cyclosporin; **AND**
7. Therapy with Prevymis will be initiated no later than 30 days post-transplantation; **AND**
8. Therapy duration with Prevymis will not exceed 100 days post-transplantation; **AND**
9. The patient has a documented contraindication to the oral formulation of Prevymis.

**When Letermovir (Prevymis) is not covered**

Letermovir (Prevymis™) is considered investigational for all other indications not listed above.

**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.

The recommended dose for Prevymis is 480 mg once a day. Prevymis may be taken by mouth in the form of a tablet or given intravenously when the patient is unable to take it by mouth. Prevymis should be initiated between day 0 and day 28 post-transplantation (before or after engraftment) and continued through day 100 post-transplantation. If oral or intravenous Prevymis is administered along with cyclosporine, the Prevymis dose should be decreased to 240 mg once daily. Prevymis injection, which contains hydroxypropyl betadex, should be used only in patients who are unable to take oral therapy, and patients should be switched to oral Prevymis as soon as they are able to take oral medications.

**Billing/Coding/Physician Documentation Information**

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

*Applicable service codes: C9399, J3490, J3590*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

**Scientific Background and Reference Sources**

U.S. Food and Drug Administration (FDA). Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/209939Orig1s000,209940Orig1s000lbl.pdf

U.S. Food and Drug Administration (FDA). Available at: https://www.fda.gov/Drugs/InformationOnDrugs/ucm587123.htm


Merck & Co., Inc. Prevymis (letermovir) injection for intravenous use, tablets for oral use. Highlights of prescribing information. January 2020. Available at:
Letermovir (Prevymis™)


Policy Implementation/Update Information

3/29/18   New policy developed. 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 medical criteria and guidelines are met. References added. (lpr)

4/16/19   Specialty Matched Consultant Advisory Panel review 3/20/2019. Changed wording of criterion #7 from “The patient has not exceeded 30 days post-transplantation” to “Therapy with Prevymis will be initiated no later than 30 days post-transplantation” for clarity. No change to policy intent. (krc)


Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.