Mass General Brigham
Health Plan

Antiviral Agents
Prevymis® (letermovir)
Sitavig® (acyclovir buccal tablet)
Effective 04/01/2023

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit (NLX)		
Specialty Limitations	N/A		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview

Prevymis (letermovir) 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).

Sitavig (acyclovir buccal tablet) is indicated for the treatment of recurrent herpes labialis (cold sores) in immunocompetent adults.

No PA	Require PA
acyclovir capsule, tablet	Prevymis® (letermovir)
acyclovir injection	Sitavig® (acyclovir buccal tablet)
cidofovir	
Cytovene® (ganciclovir injection)	
Denavir® (penciclovir)	
famciclovir	
foscarnet	
Valcyte® # (valganciclovir)	
Valtrex® # (valacyclovir)	
Xerese® (acyclovir/hydrocortisone)	
Zovirax® # (acyclovir suspension)	
Zovirax® # (acyclovir cream, ointment)	

#This is a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.

Coverage Guidelines
Authorization may be granted for members new to the plan who are currently receiving treatment with requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted for members when all the following criteria are met, and documentation is provided:

Prevymis® (letermovir)
Prescriber provides documentation of ALL of the following:
1. Appropriate diagnosis of CMV prophylaxis in allogenic HSCT
2. Member is at high risk for CMV reactivation
3. If request is for the injection formulation, clinical rationale why member cannot use tablet formulation

Sitavig® (acyclovir buccal tablet)
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis of cold sores (HSV-1, orolabial herpes, herpes labialis)
2. Adverse reaction or contraindication to oral acyclovir
3. Physician attestation of inadequate response (in a previous episode), adverse reaction, or contraindication to **BOTH** oral famciclovir and valacyclovir
4. **ONE** of the following:
    a. Quantity requested is for 2 tablets per month
    b. Medical necessity for exceeding 2 tablets per month (i.e. frequent outbreaks)

Limitations
1. Initial approvals will be granted for:
    a. Prevymis: 100 days
    b. Sitavig: 1 month
2. Reauthorizations will be granted for:
    a. Prevymis
        i. 3 months - reauthorization is received and the member has received ≤ 3 months of therapy and continues to be high risk
        ii. 6 months - reauthorization is received and the member has received ≤ 6 months of therapy and the prescriber documents active CMV viremia (no specific viral threshold needs to be met)
    b. Sitavig
        i. 6 months - reauthorization is within three months of initial approval
        ii. 1 month - reauthorization is beyond three months of initial approval and will be treated as new outbreak
3. The following quantity limits apply:

Sitavig 50 mg buccal	2 tablets per 30 days

References

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13. Famciclovir [package insert]. Weston (FL): Apotex Inc.; 2011 Mar.
14. Valacyclovir [package insert]. Morgantown (WV): Mylan Pharmaceuticals Inc.; 2011 Dec.
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17. Fishman JA, Alexander BD. Prophylaxis of infections in solid organ transplantation. In: Basow DS (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2019 Sep [cited 2020 May 18]. Available from: https://www.uptodate.com/contents/prophylaxis-of-infections-in-solid-organ-transplantation.

Review History

06/25/18 – Reviewed
06/19/19 – Approved by P&T
05/20/2020 – Reviewed and Updated May P&T; references updated; dosing updated to included oral and IV formulation; added started and stabilized statement. Effective 8/1/20.

11/16/2022 – Reviewed for Nov P&T. Separated out MH vs Comm/Exch. No clinical changes
02/08/2023 - Reviewed and updated for Feb P&T. Matched MH criteria. Added Overview table. Added Sitavig criteria and updated Prevymis criteria. Clarified approval durations. Updated references. Effective 4/1/23.