Mass General Brigham
Health Plan

Antiviral Agents
Denavir (penciclovir)
Prevymis® (letermovir)
Sitavig® (acyclovir buccal tablet)
Effective 01/02/2024

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	Prevymis vial is available through both pharmacy and medical benefits.		

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	Denavir® (penciclovir) *
acyclovir injection	Prevymis® (letermovir)
cidofovir	Sitavig® (acyclovir buccal tablet)
Cytovene® (ganciclovir injection)	
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.
*A-rated generic available. Both brand and A-rated generic require PA.

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:

Denavir® (penciclovir)
ALL of the following:
1. Diagnosis of recurrent herpes labialis (cold sores, HSV-1, orolabial herpes)
2. Member is ≥ 12 years of age
3. Inadequate response or adverse reaction to **ONE** or contraindication to **BOTH** of the following:
    a. acyclovir cream, ointment
    b. Xerese®
4. **ONE** of the following:
    a. Requested quantity is ≤ 5 grams/30 days
    b. Medical necessity for exceeding 5 grams/30 days (i.e. frequent outbreaks/large area)

Prevymis® (letermovir)
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)
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. Inadequate response (in a previous episode), adverse reaction, or contraindication to **BOTH** of the following:
    a. oral famciclovir
    b. 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)

Continuation of Therapy
Denavir (penciclovir): Reauthorization by prescriber will infer a positive response to therapy.

Prevymis, Sitavig: See below for additional information

Limitations
1. Initial approvals will be granted for:
    a. Prevymis: **100 days**
    b. Denavir (penciclovir), Sitavig: **1 month**
2. Reauthorizations will be granted for:
    a. Denavir (penciclovir): **6 months**
    b. 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)

c. 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. **Requests for Brand Name when generic is preferred:** In addition to any prior authorization requirements that may be listed above, if an A-rated generic equivalent is available, such prior authorization requests require medical records documenting an allergic response, adverse reaction, or inadequate response to the generic equivalent drug (history of allergic reaction to the inactive ingredients used in the manufacturing process of a certain drug is acceptable).
4. **Requests for generic when Brand Name is preferred:** There are some drugs for which the Plan has determined it will be cost effective to prefer the use of the Brand Name formulation. In this case, the generic equivalent formulation is considered non-preferred and requires prior authorization. These requests require medical records documenting an allergic response, adverse reaction, or inadequate response to the Brand Name formulation. For the most up to date list of drugs where the Brand Name formulation is preferred, see the MassHealth Brand Name Preferred Over Generic Drug List (BOGL) at www.mass.gov/druglist.
5. 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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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.
06/14/23 – Reviewed and updated for P&T. Admin update: Clarified that Prevymis vial is available through both pharmacy and medical benefits (dual). Effective 6/30/23
12/13/23 – Reviewed and updated for P&T. Policy update to reflect the removal of brand preferred status from Denavir (penciclovir) and added PA. Effective 1/2/24