

Clinical Policy Title:	acyclovir
Policy Number:	RxA.282
Drug(s) Applied:	Sitavig <sup>®</sup>
Original Policy Date:	02/07/2020
Last Review Date:	8/28/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

### Criteria

# I. Initial Approval Criteria

- A. Herpes Labialis (must meet all):
  - 1. Diagnosis of recurrent herpes labialis (cold sores);
  - 2. Member meets one of the following (a or b):
    - a. Trial and failure of acyclovir formulations (e.g., generic tablets, capsules or oral suspension) unless contraindicated or clinically significant adverse effects are experienced;
    - b. Documentation supports inability to swallow oral acyclovir formulations.

### **Approval Duration**

All Lines of Business (except Medicare): 1 month (2 doses)

#### II. Continued Therapy Approval

- **A.** Herpes Labialis (must meet all):
  - Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

#### **Approval Duration**

All Lines of Business (except Medicare): 12 months

# References

- 1. White ML, Chodosh J, et al. Herpes simplex virus keratitis: a treatment guideline 2014. American Academic of Ophthalmology. 2014; 1-68. Available at: <a href="https://www.aao.org/clinical-statement/herpes-simplex-virus-keratitis-treatment-guideline">https://www.aao.org/clinical-statement/herpes-simplex-virus-keratitis-treatment-guideline</a>. Accessed August 28, 2024.
- 2. Porter SM, Patterson A, Kho P. A comparison of local and systemic acyclovir in the management of herpetic disciform keratitis. Br J Ophthalmol. May 1990;74(5):283-5. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1042099/. Accessed August 28, 2024.
- 3. Balderson DE, Cai G, Fries MA, et al. A systematic review and meta-analysis to compare the efficacy of acyclovir 3% ophthalmic ointment to idoxuridine in curing herpetic keratitis by Day 7 of treatment. BMC Ophthalmol. 2015 Apr;15:42. Available at: <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4451880/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4451880/</a>. Accessed August 28, 2024.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	02/07/2020

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.



<ol> <li>Policy was reviewed:         <ul> <li>Policy title table was updated:</li> <li>Clinical Policy Title was updated to</li> <li>"acyclovir"; Drug(s) Applied was updated to "Sitavig®, Avaclyr™"; Line of Business Policy Applies to was updated to "All".</li> </ul> </li> <li>Clinical policy was updated: Approval duration was updated for both Initial and Continued Approval Criteria; Continued Approval was rephrased to "Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy".; Included failure of 2 generic drugs for initial approval.</li> <li>References were updated.</li> </ol>	08/01/2020	09/14/2020
<ol> <li>Policy was reviewed:         <ol> <li>Initial Approval Criteria I.A.4.a.1-3 were consolidated into I.A.4.a, "Failure of two of the following generic drugs unless contraindicated or clinically significant adverse effects are experienced: acyclovir, valacyclovir, or famciclovir tablets or capsules;".</li> <li>Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance".</li> </ol> </li> <li>Continued Therapy Approval Criteria II.B.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance".</li> <li>References were reviewed and updated.</li> </ol>	07/14/2021	09/14/2021
Policy was reviewed:  1. Policy updated to remove Avaclyr™ as it is no longer available on the market.	3/15/2022	7/18/2022

© 2024 RxAdvance Corporation. All rights reserved. This policy contains the confidential and proprietary information of RxAdvance. Unauthorized reproduction, distribution, modification, display, storage, transmission, or use of this policy or any information contained herein is strictly prohibited.

Revised 08/2024 Page 2 of 3 *v 2.0.01.1* 



References were reviewed and updated.		
Policy was reviewed:  1. Initial Approval Criteria 1.A.3.a:    Updated from Failure of two of    the following generic drugs    unless contraindicated or    clinically significant adverse    effects are experienced:    acyclovir, valacyclovir, or    famciclovir tablets or capsules to    Trial and failure of acyclovir    formulations ( e.g., generic    tablets, capsules or oral    suspension) unless    contraindicated or clinically    significant adverse effects are    experienced;  2. Initial Approval Criteria I.A.3.b:    Updated from Documentation    supports inability to use (i.e.,    inability to swallow) generic    acyclovir, valacyclovir, or    famciclovir tablets or capsules to    Documentation supports inability    to swallow oral acyclovir    formulations.  3. References were reviewed and    updated.	4/13/2023	07/13/2023
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed:  1. Removed age restrictions.  2. Removed dose restrictions.  3. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days.  4. Removed reauthorization requirement for positive response to therapy.  5. Updated approval duration verbiage.  6. References were reviewed and updated.	8/28/2024	9/13/2024

Revised 08/2024 Page 3 of 3 *v 2.0.01.1*