Clinical Policy Title:	acyclovir
Policy Number:	RxA.282
Drug(s) Applied:	Sitavig®
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)**:**

1. 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: https://www.aao.org/clinical-statement/herpes-simplex-virus-keratitis-treatment-guideline. 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: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4451880/. Accessed August 28, 2024.

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

Policy was reviewed: 1. Policy title table was updated: Clinical Policy Title was updated to "acyclovir"; Drug(s) Applied was updated to "Sitavig®, Avaclyr™"; Line of Business Policy Applies to was updated to "All". 2. 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. 3. References were updated.	08/01/2020	09/14/2020
Policy was reviewed: 1. 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;”. 2. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 3. Continued Therapy Approval Criteria II.B.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 4. References were reviewed and updated.	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

2. 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