Clinical Policy: Acyclovir Buccal Tablet (Sitavig)

Reference Number: CP.PMN.210
Effective Date: 11.16.16
Last Review Date: 11.22
Line of Business: Commercial, HIM, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Acyclovir buccal tablet (Sitavig®) is a herpes simplex virus deoxynucleoside analog of DNA polymerase inhibitor.

FDA Approved Indication(s)

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

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Sitavig is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Herpes Labialis (must meet all)**:**

1. Diagnosis of recurrent herpes labialis (cold sores);
2. Age ≥ 18 years;
3. Member must use preferred formulary acyclovir formulation (e.g., generic tablets, capsules or oral suspension) unless contraindicated, clinically significant adverse effects are experienced, or documentation supports inability to swallow oral formulations;
4. Dose does not exceed 50 mg (1 tablet).

Approval duration: 1 month (up to 2 doses)

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Herpes Labialis (must meet all)**:**

1. Re-authorization is not permitted. Members must meet the initial approval criteria.

Approval duration: Not applicable

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
acyclovir (Zovirax®) off-label	**Herpes Labialis** Initial episode: 200 mg PO 5 times daily for 7-10 days OR 400 mg PO TID for 7-10 days Recurrence: 400 mg PO TID for 5 days OR 800 mg PO BID for 5 days OR 800 mg TID for 2 days Chronic suppression: 400 mg PO BID	4,000 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): hypersensitivity to acyclovir, milk protein concentrate, or any other component of the product
- Boxed warning(s): none reported

Appendix D: General Information

- Sitavig pivotal trial inclusion criteria for recurrent herpes labialis required at least 4 herpes episodes in the previous year.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Treatment of recurrent herpes labialis (cold sores)	One 50 mg buccal tablet applied as a single dose to the upper gum region (canine fossa)	50 mg

VI. Product Availability

Buccal tablet: 50 mg

VII. References

1. Sitavig Prescribing Information. Charleston, SC: EPI Health, LLC; December 2019. Available at: http://sitavig.com/prescribing-information/. Accessed July 25, 2022.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2020. Available at: http://www.clinicalpharmacology-ip.com/. Sitavig Drug Monograph. Clinical Pharmacology. Accessed July 25, 2022.
3. Cernik C, Gallina K, Brodell R. The Treatment of Herpes Simplex Infections: An Evidence-Based Review. Arch Intern Med. 2008;168(11):1137-1144. doi:10.1001/archinte.168.11.1137
4. Bieber T, Chosidow O, Bodsworth N, et al. Efficacy and safety of acyclovir mucoadhesive buccal tablet in immunocompetent patients with labial herpes (LIP): A double-blind, placebo-controlled, self-initiated trial. J Drugs Dermatol. 2014;13(7):791-798.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created: adopted from CP.CPA.153 acyclovir buccal tab (Sitavig). Added new acyclovir dosage form, ophthalmic ointment (Avaclyr), to policy along with relevant indication, dosage forms, dosing, and contraindications; created criteria for herpes keratitis; Changed Sitavig approval from One time to One month (up to 2 doses) since the package comes with two buccal tablets with one back-up in the event of a failed administration.	04.30.19	08.19
Q4 2019 annual review: no significant changes; references reviewed and updated.	08.24.19	11.19
Q4 2020 annual review: added HIM line of business; references reviewed and updated.	08.09.20	11.20
Q4 2021 annual review: removed Avaclyr as the product is no longer on the market; updated reference for HIM off-label use to HIM.PA.154 (replaces HIM.PHAR.21); references reviewed and updated.	07.22.21	11.21
Q4 2022 annual review: for Section IA revised language to "Member must use preferred formulary acyclovir formulation…"; for Section IIA, changed reauthorization to not permitted; references reviewed and updated. Template changes applied to other diagnoses/indications.	07.25.21	11.22

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to

applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.