

PHARMACY COVERAGE GUIDELINE

SITAVIG® (acyclovir) Generic Equivalent (if available)

This Pharmacy Coverage Guideline (PCG):

- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively “Service”) is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider’s judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member’s benefit plan; and
- Is subject to change as new information becomes available.

Scope

- This PCG applies to Commercial and Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance

- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The “Criteria” section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member’s benefit plan.
- The “Description” section describes the Service.
- The “Definition” section defines certain words, terms or items within the policy and may include tables and charts.
- The “Resources” section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require prior authorization is available at www.azblue.com/pharmacy. You must fully complete the [request form](#) and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

Criteria:

- **Criteria for initial therapy:** Sitavig (acyclovir) and/or generic equivalent (if available) is considered **medically necessary** and will be approved when **ALL** the following criteria are met:
 1. Individual is 18 years of age or older
 2. Individual has a confirmed diagnosis of **recurrent herpes labialis (cold sore) with a well-defined prodrome of symptoms** (e.g., pain, tingling, burning that precedes appearance of vesicles) in an immunocompetent individual
 3. Individual has at least 4 herpetic episodes per year

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4. **If available:** Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] ([see Definitions section](#))
5. Individual has documented failure, contraindication per FDA label, intolerance, or is not a candidate for **TWO** of the following:
 - a. Generic acyclovir
 - b. Generic famciclovir
 - c. Generic valacyclovir

Initial approval duration: Total of 4 tablets for 12 months

- **Criteria for continuation of coverage (renewal request):** Sitavig (acyclovir) and/or generic equivalent (if available) is considered **medically necessary** and will be approved when **ALL** the following criteria are met (**samples are not considered for continuation of therapy**):

1. Individual continues to have recurrent herpes labialis (cold sore) with a well-defined prodrome of symptoms (e.g., pain, tingling, burning that precedes appearance of vesicles)
2. Individual has documentation of positive clinical response to therapy defined as reduced pain, burning, tingling, redness, and pruritus
3. **If available:** Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] ([see Definitions section](#))

Renewal duration: Total of 4 tablets for 12 months

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. **Off-Label Use of Non-Cancer Medications**
 2. **Off-Label Use of Cancer Medications**
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Description:

Sitavig (acyclovir) buccal tablet is indicated for the treatment of recurrent herpes labialis (cold sores) in immunocompetent adults. The safety and effectiveness of Sitavig (acyclovir) in pediatric patients have not been established. The ability of pediatric patients to comply with the application instructions has not been evaluated. Use in younger children is not recommended due to potential risk of choking. Use of Sitavig (acyclovir) resulted in reduction in the duration of symptoms by a half day.

Acyclovir is a synthetic purine nucleoside analogue active against herpes viruses.

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Herpes simplex virus type 1 (HSV-1) and Herpes labialis:

HSV-1 is a member of the family of herpesviruses that includes not only HSV-1, but also HSV-2, cytomegalovirus (CMV), Epstein Barr virus, and human herpes viruses 6, 7, and 8. The principal clinical manifestation of primary HSV-1 infection is gingivostomatitis, sometimes associated with pharyngitis.

HSV-1 causes vesicular lesions of the lips and oral mucosa known as herpes labialis or cold sores. After primary infection, HSV lives in a latent state in ganglion neurons and can reactivate. Reactivation of prior HSV-1 infection occurs in the trigeminal sensory ganglion. Reactivation may lead to cutaneous, and more commonly, mucocutaneous disease, known as herpes labialis, which occurs along the vermilion border of the lip.

Cold sores are painful blisters that form on or near the lips and inside of the mouth caused by an infection with HSV-1, they are different from canker sores. Canker sores are painful red or white sores that can form in the mouth and on the tongue, but they do not form blisters or scab over.

The majority of patients are aware of prodromal symptoms that herald the onset of a reactivation episode, symptoms include pain, burning, tingling, redness, and pruritus that precede vesicle formation. The frequency and severity of reactivation is determined by many factors, including stress or any underlying immunodeficiency, such as HIV infection.

In the immunocompetent host, recurrent episodes are usually of shorter duration than the primary episode. The median time from onset of prodromal symptoms to healing of the lesion is approximately five days. The frequency and severity of recurrent infections are greater in the immunocompromised host, who is also at risk for disseminated HSV-1 infection to uncommon sites, such as the lungs or gastrointestinal tract.

Rapid initiation of antiviral therapy for patients with episodic HSV-1 and a well-defined prodrome may result in earlier healing of lesions, decreased pain, and a shorter duration. Choice of agents includes: acyclovir; famciclovir; and valacyclovir.

Chronic suppressive therapy decreases the number of recurrences of herpes labialis among patients with frequent (more than four episodes per year) recurrences of HSV. Patients with multiple painful or disfiguring lesions who do not have an identifiable prodrome or patients who have recurrences associated with serious complications, such as recurrent aseptic meningitis, may also benefit from chronic suppressive therapy.

Definitions:

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting
[MedWatch Forms for FDA Safety Reporting | FDA](#)

Resources:

Sitavig (acyclovir) delayed release buccal tablet product information, revised by EPI Health, Inc. 12-2019. Available at DailyMed <http://dailymed.nlm.nih.gov>. Accessed July 25, 2025.

Wald A, Johnston C. Treatment and prevention of herpes simplex virus type 1 in immunocompetent adolescents and adults. In: UpToDate, Hirsch MS, Mitty J (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at <http://uptodate.com>. Literature current through July 2025. Topic last updated July 15, 2024. Accessed August 19, 2025.

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