BlueCross BlueShield of Arizona
An Independent Licensee of the Blue Cross and Blue Shield Association

PHARMACY COVERAGE GUIDELINES	**ORIGINAL EFFECTIVE DATE: 11/20/14**
SECTION: DRUGS	**LAST REVIEW DATE: 11/16/17**
	LAST CRITERIA REVISION DATE: 11/16/17
	ARCHIVE DATE:

SITAVIG® (acyclovir) buccal tablet

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. All requested data must be provided. Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

SITAVIG® (acyclovir) buccal tablet (cont.)

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.

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

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 herpesviruses 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 vermillion 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 from 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

SITAVIG® (acyclovir) buccal tablet (cont.)

- 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 (200 or 400 mg five times daily)
        - Famciclovir (750 mg twice daily for one day or 1500 mg as a single dose)
        - Valacyclovir (2 g twice daily for one day)

- 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

Sitavig (acyclovir) oral buccal tablet

Medication class:
Antiviral agent, topical

FDA-approved indication(s):
- Treatment of recurrent herpes labialis (cold sores) in immunocompetent adults

Recommended Dose:
- Apply one 50 mg tablet as a single dose to the upper gum region (canine fossa)
- It should be applied 1 hour after onset of prodromal symptoms and before appearance of any signs of herpes labialis lesions
- The tablet should be placed on the same side of the mouth as the herpes labialis symptoms

Maximum dosage
- Not stated

Available Dosage Forms:
- 50 mg buccal tablets

Warnings, Precautions, and other Clinical Information:
- If the tablet does not adhere or falls off within the first 6 hours, the same tablet can be repositioned, if it cannot be repositioned a new tablet should be placed
- If the tablet is swallowed within the first 6 hours, a new tablet should be applied
- A new tablet does not need to be reapplied if it falls out or is swallowed after 6 hours
- The safety of Sitavig has not been studied in immunocompromised patients
- The mean and median duration of recurrent herpes labialis episodes are approximately half a day shorter with Sitavig than with placebo

SITAVIG® (acyclovir) buccal tablet (cont.)

Criteria:

- **Criteria for initial therapy:** Sitavig (acyclovir) is considered ***medically necessary*** for individuals with medical record documentation of **ALL** of the following:

  1. Individual is 18 years of age or older

  2. A confirmed diagnosis of recurrent herpes labialis (cold sore) in an immunocompetent individual

  3. Individual has failure, contraindication, or intolerance to **TWO** of the following preferred step therapy agents:
     - Preferred step therapy agents include:
       - Generic acyclovir (Zovirax)
       - Generic famciclovir (Famvir)
       - Generic valacyclovir (Valtrex)

  4. There are **NO** contraindications
     - Contraindications include:
       - Hypersensitivity to acyclovir, milk protein concentrate, or any other component of the product

  Initial approval duration: Total of 4 tablets for 12 months

- **Criteria for continuation of coverage (renewal request):** Sitavig (acyclovir) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual's condition responded while on therapy
     - Response is defined as:
       - Reduced pain, burning, tingling, redness, and pruritus

  2. Individual has not developed any contraindications or other significant level 4 adverse drug effects that may exclude continued use
     - Contraindications as listed in the criteria for initial therapy section

  Renewal duration: Total of 4 tablets for 12 months

Resources:

Sitavig. Package Insert. Reference ID 3292406. Revised by manufacturer 04/2013. Accessed 10-23-2014, 10-13-2015, 10-18-2016

SITAVIG® (acyclovir) buccal tablet (cont.)

UpToDate: Treatment of herpes simplex virus type 1 infection in immunocompetent patients. Current through Sep 2017. https://www-uptodate-com.mwu.idm.oclc.org/contents/treatment-of-herpes-simplex-virus-type-1-infection-in-immunocompetent-patients?source=search_result&search=cold%20sores&selectedTitle=1~150#H26

UpToDate: Clinical manifestations and diagnosis of herpes simplex virus type 1 infection. Current through Sep 2017. https://www-uptodate-com.mwu.idm.oclc.org/contents/clinical-manifestations-and-diagnosis-of-herpes-simplex-virus-type-1-infection?source=search_result&search=cold%20sores&selectedTitle=2~150

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Fax completed prior authorization request form to 602-864-3126 or email to pharmacyprecert@azblue.com.
Call 866-325-1794 to check the status of a request.
All requested data must be provided. **Incomplete forms or forms without the chart notes will be returned.**
Pharmacy Coverage Guidelines are available at www.azblue.com/pharmacy.

Pharmacy Prior Authorization Request Form

Do not copy for future use. Forms are updated frequently.
REQUIRED: Office notes, labs, and medical testing relevant to the request that show medical justification are required.

Member Information

Member Name (first & last):	Date of Birth:	Gender:	BCBSAZ ID#:
Address:	City:	State:	Zip Code:

Prescribing Provider Information

Provider Name (first & last):	Specialty:	NPI#:	DEA#:
Office Address:	City:	State:	Zip Code:
Office Contact:	Office Phone:	Office Fax:	

Dispensing Pharmacy Information

Pharmacy Name:	Pharmacy Phone:	Pharmacy Fax:

Requested Medication Information

Medication Name:	Strength:		Dosage Form:
Directions for Use:	Quantity:	Refills:	Duration of Therapy/Use:

☐ Check if requesting **brand** only ☐ Check if requesting **generic**

☐ Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)

Turn-Around Time For Review

☐ Standard ☐ Urgent. Sign here: _____ ☐ Exigent (requires prescriber to include a written statement)

Clinical Information

1. **What is the diagnosis? Please specify below.**

   ICD-10 Code: _____ **Diagnosis Description:** _____

2. ☐ Yes ☐ No **Was this medication started on a recent hospital discharge or emergency room visit?**

3. ☐ Yes ☐ No **There is absence of ALL contraindications.**

4. **What medication(s) has the individual tried and failed for this diagnosis? Please specify below.**
Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.

Medication Name, Strength, Frequency	Dates started and stopped or Approximate Duration	Describe response, reason for failure, or allergy

5. **Are there any supporting labs or test results? Please specify below.**

Date	Test	Value

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Pharmacy Prior Authorization Request Form

6. Is there any additional information the prescribing provider feels is important to this review? Please specify below.
For example, explain the negative impact on medical condition, safety issue, reason formulary agent is not suitable to a specific medical condition, expected adverse clinical outcome from use of formulary agent, or reason different dosage form or dose is needed.

Signature affirms that information given on this form is true and accurate and reflects office notes

Prescribing Provider's Signature: Date:

Please note: Some medications may require completion of a drug-specific request form.

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Office notes, labs, and medical testing relevant to the request that show medical justification are required.