PRIOR AUTHORIZATION CRITERIA

BRAND NAME*
(generic)

SITAVIG
(acyclovir buccal tablet)

Status: CVS Caremark Criteria
Type: Initial Prior Authorization with Quantity Limit ***Ref # 1545-C***

** Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated. OTC products are not included unless otherwise stated.*

FDA-APPROVED INDICATIONS

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

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug is being prescribed for the treatment of recurrent herpes labialis (cold sores) in an immunocompetent adult

AND

- The patient has experienced an inadequate treatment response to a generic oral antiviral medication (e.g., acyclovir, famciclovir, valacyclovir)

OR

- The patient has experienced an intolerance to a generic oral antiviral medication (e.g., acyclovir, famciclovir, valacyclovir)

OR

- The patient has a contraindication that would prohibit a trial of a generic oral antiviral medication (e.g., acyclovir, famciclovir, valacyclovir)

Quantity Limits apply.

RATIONALE

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Sitavig is indicated for the treatment of recurrent herpes labialis (cold sores) in immunocompetent adults.

According to the treatment guidelines for herpes labialis (cold sores), oral acyclovir, valacyclovir, and famciclovir are effective in treating acute recurrence of herpes labialis. Recurrences of herpes labialis may be diminished with daily oral acyclovir or valacyclovir. Topical treatment for herpes labialis is less effective than oral treatment.[4,5] Topical acyclovir, penciclovir, and docosanol are optional treatments for recurrent herpes labialis, but they are less effective than oral treatment.[4] Therefore, a trial of a generic oral antiviral medication (e.g., acyclovir, famciclovir, valacyclovir) will be required.

One Sitavig 50 mg buccal tablet should be applied as a single dose to the upper gum region (canine fossa). The tablet should be applied with a dry finger immediately after taking it out of the blister. The tablet should be placed to the upper gum just above the incisor tooth (canine fossa) and held in place with slight pressure over the upper lip for 30 seconds to ensure adhesion. If Sitavig does not adhere or falls off within the first 6 hours, the same tablet should be repositioned immediately. If the tablet cannot be repositioned, a new tablet should be placed. If Sitavig is swallowed within the first 6 hours, the patient should drink a glass of water and a new tablet should be applied. Sitavig does not need to be reapplied if the tablet falls out or is swallowed after the first 6 hours.

Recurrent labial herpes affects roughly one third of the US population, and these patients typically experience 1 to 6 episodes per year.[4,5] The quantity limit is set to allow for the treatment of one herpes labialis (cold sore) episode per month.

Sitavig is indicated for acute use of herpes labialis; therefore the retail and mail limit will be the same.

REFERENCES

1. Sitavig [package insert]. Charleston, SC: EPI Health, LLC; December, 2019.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. http://online.lexi.com/. Accessed December 2020.
3. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. http://www.micromedexsolutions.com/. Accessed December 2020.
4. Cernik C, Gallina K et al. The Treatment of Herpes Simplex Infections – An Evidence-Based Review. *Arch Intern Med*. 2008; 168(11):1137-1144.
5. Usatine RP, Tinitigan R. Nongenital Herpes Simplex Virus. *Am Fam Physician*. 2010; 82(9):1075-1082.

Written by:	UM Development (KM)
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CRITERIA FOR APPROVAL

1	Is the requested drug being prescribed for the treatment of recurrent herpes labialis (cold sores) in an immunocompetent adult? [If no, then no further questions.]	Yes	No
2	Has the patient experienced an inadequate treatment response to a generic oral antiviral medication (e.g., acyclovir, famciclovir, valacyclovir)? [If yes, then skip to question 5.]	Yes	No
3	Has the patient experienced an intolerance to a generic oral antiviral medication (e.g., acyclovir, famciclovir, valacyclovir)? [If yes, then skip to question 5.]	Yes	No
4	Does patient has a contraindication that would prohibit a trial of a generic oral antiviral medication (e.g., acyclovir, famciclovir, valacyclovir)? [If no, then no further questions.]	Yes	No
5	Does the patient require more than the plan allowance of 2 tablets of Sitavig (acyclovir buccal tablet) per month? [RPh Note: If yes, then deny and enter a partial approval for 2 tablets per 25 days.]	Yes	No

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS – DO NOT USE FOR MEDICARE PART D**
1.	Go to 2	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you meet all of these conditions:

			- You are an adult - You have a normal immune response - You are being treated for recurrent cold sores Your request has been denied based on the information we have. [Short Description: no approvable diagnosis, not an adult with normal immune response]
2.	Go to 5	Go to 3	
3.	Go to 5	Go to 4	
4.	Go to 5	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you have tried a generic oral antiviral medication and it either did not work for you, or you cannot use it. Your request has been denied based on the information we have. [Short Description: No inadequate response, intolerance or Contraindication to a generic oral antiviral medication]
5.	Deny	Approve, 12 months 2 tablets/25 days*	You have requested more than the maximum quantity allowed by your plan. Current plan approved criteria cover up to: - 2 tablets per month of Sitavig You have been approved for the maximum quantity that your plan covers for a duration of 12 months. Your request for additional quantities of the requested drug and strength has been denied. [Short Description: Over max quantity]

** The duration of 25 days is used for a 30-day fill period to allow time for refill processing. This drug is indicated for short-term acute use; therefore, the 30-day limit will be the same as the 90-day limit*