Pharmacy Policy Bulletin J-0688 Acyclovir Topical Cream Products – Commercial	
Number: J-0688	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☐ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.):** **1.** Other Managed Prior Authorization = Yes w/ Prior Authorization
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-0688-010	**Original Date:** 01/31/2018
Effective Date: 04/25/2025	**Review Date:** 04/09/2025

Drugs Product(s):	• Xerese (acyclovir 5% and hydrocortisone 1%) topical cream • Zovirax (acyclovir) topical cream

FDA-Approved Indication(s):	• Xerese topical cream
	  ○ Early treatment of recurrent herpes labialis (cold sores) to reduce the likelihood of ulcerative cold sores and to shorten the lesion healing time in adults and children (6 years of age and older)
	• Zovirax (acyclovir) topical cream
	  ○ Treatment of recurrent herpes labialis (cold sores) in immunocompetent adults and adolescents 12 years of age and older

Background:	• Xerese is a combination of acyclovir, a herpes simplex virus (HSV) deoxynucleoside analog DNA polymerase inhibitor, and hydrocortisone, a corticosteroid. The antiviral compound acyclovir has inhibitory activity against HSV-1 and HSV-2.
	  ○ Acyclovir inhibits viral DNA synthesis and must be phosphorylated intracellularly to be active. Acyclovir is converted to the monophosphate by viral thymidine kinase (TK), then to diphosphate by cellular guanylate kinase, and finally to the triphosphate by various cellular enzymes. Acyclovir triphosphate stops replication of herpes viral DNA by the following 3 mechanisms: competitive inhibition of viral DNA polymerase, incorporation into and termination of the growing viral DNA chain, and inactivation of the viral DNA polymerase.
	  ○ Hydrocortisone is the main glucocorticoid secreted by the adrenal cortex. It is used topically for its anti-inflammatory effects.
	• Nongenital herpes simplex virus type 1 (HSV-1) is a common infection usually transmitted during childhood via nonsexual contact. Most of these infections involve the oral mucosa or lips (for example, herpes labialis). Herpes simplex virus type 1 diagnosis is usually made by the appearance of the lesions (grouped vesicles or ulcers on an erythematous base) and patient history.
	• Routine treatment for healthy individuals with mild-to-moderate recurrent episodes of HSV-1 is not recommended. Most episodes of herpes labialis are self-limiting.

	• Oral acyclovir, valacyclovir, and famciclovir are effective in treating acute recurrence of herpes labialis (cold sores). Recurrences of herpes labialis may be diminished with daily oral acyclovir or valacyclovir. Topical acyclovir, penciclovir, and docosanol are optional treatments for recurrent herpes labialis, but they are less effective than oral treatment.
	• Prescribing Considerations:
	  ○ Xerese is intended for cutaneous use only for herpes labialis of the lips and around the mouth. It should not be used in the eye, inside the mouth or nose, or on the genitals.
	  ○ Topically apply Xerese 5 times per day for 5 days. Topically apply Zovirax (acyclovir) cream 5 times per day for 4 days.
	  ○ Therapy should be initiated as early as possible after the first signs and symptoms (specifically, during the prodrome or when lesions appear)

Approval Criteria

I. Initial Authorization

A. Xerese topical cream

When a benefit, coverage of Xerese may be approved when all of the following criteria are met **(1. through 5.)**:

1. The member is 6 years of age or older.
2. The member has a diagnosis of recurrent herpes labialis (cold sores). (ICD-10: B00.1)
3. The member has experienced therapeutic failure or intolerance to generic oral acyclovir.
4. The member has experienced therapeutic failure or intolerance to one (1) of the following generic oral antivirals, or both are contraindicated **(a. or b.)**:
  a. valacyclovir
  b. famciclovir
5. The member has experienced therapeutic failure or intolerance to plan-preferred generic acyclovir 5% ointment and hydrocortisone 1% cream, available separately and used together.

B. Zovirax (acyclovir) topical cream

When a benefit, coverage of Zovirax (acyclovir) topical cream may be approved when all of the following criteria are met **(1. through 5.)**:

1. The member is 12 years of age or older.
2. The member has a diagnosis of recurrent herpes labialis (cold sores). (ICD-10: B00.1)
3. The member has experienced therapeutic failure or intolerance to generic oral acyclovir.
4. The member has experienced therapeutic failure or intolerance to one (1) of the following generic oral antivirals, or both are contraindicated **(a. or b.)**:
  a. valacyclovir
  b. famciclovir
5. The member has experienced therapeutic failure or intolerance to plan-preferred generic acyclovir 5% ointment.

II. Reauthorization

When a benefit, reauthorization of an acyclovir topical cream product may be approved when all of the following criteria are met **(A., B., and C.)**:

A. The prescriber attests that the member has experienced positive clinical response to therapy.
B. If the request is for Xerese, the member has experienced therapeutic failure or intolerance to plan-preferred generic acyclovir 5% ointment and hydrocortisone 1% cream, available separately and used together.
C. If the request is for Zovirax (acyclovir), the member has experienced therapeutic failure or intolerance to plan-preferred generic acyclovir 5% ointment.

III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.
II. For Commercial members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial Plans: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

None

References:

1. Xerese [package insert]. Bridgewater, NJ: Bausch Health US, LLC; August 2020.
2. Zovirax [package insert]. Bridgewater, NJ: Bausch Health US, LLC; February 2021.
3. Usatine R, Tinitigan R. Nongenital herpes simplex virus. American Family Physician. Available at: https://www.aafp.org/afp/2010/1101/p1075.html. Accessed March 06, 2025.