

## PRIOR AUTHORIZATION POLICY

- POLICY:** Topical Acyclovir Products Prior Authorization Policy
- Zovirax<sup>®</sup> (acyclovir 5% cream –Bausch Health, generic)
  - Zovirax<sup>®</sup> (acyclovir 5% ointment – Bausch Health, generic)

**REVIEW DATE:** 07/31/2024

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### OVERVIEW

Acyclovir 5% cream (Zovirax, generic) is indicated for the treatment of **recurrent herpes labialis (cold sores)** in immunocompetent patients  $\geq 12$  years of age.<sup>1</sup>

Acyclovir 5% ointment (Zovirax, generics) is indicated for the following uses:<sup>2</sup>

- **Genital herpes**, initial treatment.
- **Limited non-life-threatening mucocutaneous herpes simplex virus infections**, in immunocompromised patients.

### POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of topical acyclovir products. All approvals are provided for the duration noted below.

**Automation:** None.

### RECOMMENDED AUTHORIZATION CRITERIA

**I.** Coverage of acyclovir 5% cream (Zovirax 5% cream, generic) is recommended in those who meet the following criteria:

#### FDA-Approved Indication

- 1. Herpes Labialis (Cold Sores).** Approve for 1 year if the patient meets BOTH of the following (A and B):
  - A) Patient is  $\geq 12$  years of age; AND
  - B) Patient is immunocompetent.

**II.** Coverage of acyclovir 5% ointment (Zovirax 5% ointment, generic) is recommended in those who meet one of the following criteria:

#### FDA-Approved Indications

- 1. Genital Herpes.** Approve for 1 year if the patient meets ONE of the following (A or B):
  - A) Generic acyclovir 5% ointment is requested; OR
  - B) Patient meets BOTH of the following (i and ii):
    - i. Patient has tried generic acyclovir 5% ointment; AND
    - ii. Patient cannot use the generic product due to a formulation difference in the inactive ingredient(s) [e.g., difference in buffers, emollients, emulsifiers, preservatives, surfactants]

07/31/2024

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between the brand and the bioequivalent generic product which, per the prescriber, would result in a significant allergy or serious adverse reaction.

2. **Limited Non-Life-Threatening Mucocutaneous Herpes Simplex Virus Infections.** Approve for 1 year if the patient meets BOTH of the following (A and B):
  - A) Patient is immunocompromised; AND
  - B) Patient meets ONE of the following (i or ii):
    - i. Generic acyclovir 5% ointment is requested; OR
    - ii. Patient meets BOTH of the following (a and b):
      - a) Patient has tried generic acyclovir 5% ointment; AND
      - b) Patient cannot use the generic product due to a formulation difference in the inactive ingredient(s) [e.g., difference in buffers, emollients, emulsifiers, preservatives, surfactants] between the brand and the bioequivalent generic product which, per the prescriber, would result in a significant allergy or serious adverse reaction.

### CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of topical acyclovir products are not recommended in the following situation:

1. **Shingles (Herpes Zoster).** Shingles is a viral infection caused by the varicella zoster virus, the same virus that causes chickenpox.<sup>3</sup> The Centers for Disease Control and Prevention cite the use of oral antivirals (acyclovir capsules/tablets/suspension, famciclovir tablets, and valacyclovir caplets) for the treatment of shingles. Oral antivirals speed healing and reduce the risk of complications. Topical antivirals are not noted as treatment options for shingles.
2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

### REFERENCES

1. Zovirax<sup>®</sup> cream [prescribing information]. Bridgewater, NJ: Bausch Health; February 2021.
2. Zovirax<sup>®</sup> ointment [prescribing information]. Bridgewater, NJ: Bausch Health; October 2020.
3. Centers for Disease Control and Prevention – Shingles. Available at: <https://www.cdc.gov/shingles/about/treatment.html>. Updated May 2023. Accessed on July 25, 2024.