

Drug Policy

Policy: SD	Zovirax Topical Prior Authorization <ul style="list-style-type: none"> • Zovirax® (acyclovir 5% cream – Valeant, generics) • Acyclovir 5% ointment 	Annual Review Date: 05/18/2023 Last Revised Date: 05/18/2023
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OVERVIEW

Acyclovir 5% cream (Zovirax, generic) is indicated for the treatment of **recurrent herpes labialis (cold sores)** in immunocompetent adults and adolescents ≥ 12 years of age.

Acyclovir 5% ointment (Zovirax, generics) is indicated for the following uses:

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

POLICY STATEMENT

This policy involves the use of Zovirax 5% cream and Acyclovir 5% ointment (Zovirax, generics). Prior authorization is recommended for pharmacy benefit coverage of Zovirax 5% cream and Acyclovir 5% ointment. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

I. Coverage of Acyclovir 5% cream (Zovirax 5% cream, generics) is recommended in those who meet the following criterion:

FDA-Approved Indication

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

Initial Approval/ Extended Approval.

- A) *Initial Approval:* 1 year (365 days)
- B) *Extended Approval:* 1 year (365 days)

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II. Coverage of acyclovir 5% ointment is recommended in those who meet the following criteria:

FDA-Approved Indications

1. **Genital Herpes.** Approve for 1 year.
2. **Limited Non-Life-Threatening Mucocutaneous Herpes Simplex Virus Infections.** Approve for 1 year if the patient is immunocompromised.

Initial Approval/ Extended Approval.

- A) *Initial Approval:* 1 year (365 days)
- B) *Extended Approval:* 1 year (365 days)

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Acyclovir 5% cream (Zovirax cream, generics) and acyclovir 5% ointment (Zovirax ointment, generics) has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. **Shingles (Herpes Zoster).** Shingles is a viral infection caused by the varicella zoster virus, the same virus that causes chickenpox.³ 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.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. World Health Organization – Herpes simplex virus. Available at: <http://www.who.int/mediacentre/factsheets/fs400/en/> Updated January 2017. Accessed on June 4, 2018.
2. Centers for Disease Control and Prevention (CDC) – 2015 Sexually transmitted disease treatment guidelines. Available at: <http://www.cdc.gov/std/tg2015/herpes.htm>. Updated June 2015. Accessed on June 4, 2018.

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3. Opstelten W, Neven AK, Eekhof J. Treatment and prevention of herpes labialis. *Can Fam Physician*. 2008;54:1683-1687.
4. Cernik C, Gallina K, Brodell RT. The treatment of herpes simplex infections. An evidence-based review. *Arch Intern Med*. 2008;168(11):1137-1144.
5. Zovirax® cream [prescribing information]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; January 2017.
6. Zovirax® ointment [prescribing information]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; January 2017.
7. Centers for Disease Control and Prevention – Shingles. Available at: <http://www.cdc.gov/shingles/about/prevention-treatment.html>. Updated January 2018. Accessed on June 4, 2018.
8. National Institute of Health, National Institute of Neurological Disorders and Stroke – Shingles: Hope through research. Available at: https://www.ninds.nih.gov/Disorders/Patient-Caregiver-Education/Hope-Through-Research/Shingles-Hope-Through-Research#3223_8. Updated March 2018. Accessed on June 4, 2018.