

PRIOR AUTHORIZATION POLICY

POLICY: Topical Acyclovir Cream and Ointment Prior Authorization Policy

- Zovirax® (acyclovir 5% cream – Valeant, generics)
- Zovirax® (acyclovir 5% ointment – Valeant, generics)

REVIEW DATE: 06/24/2020

OVERVIEW

Acyclovir 5% cream (Zovirax, generics) is indicated for the treatment of recurrent herpes labialis (cold sores) in immunocompetent adults and adolescents 12 years of age and older.¹ Acyclovir 5% ointment (Zovirax, generics) is indicated in the management of initial genital herpes and in limited non-life-threatening mucocutaneous herpes simplex virus infections in immunocompromised patients.²

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of acyclovir 5% cream and acyclovir 5% ointment. All approvals are provided for the duration noted below. For the ointment, a trial of generic acyclovir 5% ointment is required prior to approval of brand Zovirax 5% ointment.

Automation: None.

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 both of the following criteria (A and B):
 - A) Patient is ≥ 12 years of age; AND
 - B) Patient is immunocompetent.

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

FDA-Approved Indications

- 1. Genital Herpes.** Approve for 1 year if the patient meets one of the following criteria (A or B):
 - A) Generic acyclovir 5% ointment is requested; OR
 - B) If brand Zovirax 5% ointment is requested, the patient meets both of the following criteria (i and ii):
 - i. Patient has tried generic acyclovir 5% ointment; AND
 - ii. Patient cannot use the generic product to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] 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 one of the following criteria (A and B):
- A) Patient is immunocompromised; AND
 - B) Patient meets one of the following criteria (i or ii):
 - i. Generic acyclovir 5% ointment is requested; OR
 - ii. If brand Zovirax 5% ointment is request, the patient meets both of the following criteria (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 dyes, fillers, preservatives] 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 acyclovir 5% cream and acyclovir 5% ointment are not recommended in the following situation:

1. **Shingles.** Shingles is a viral infection caused by the varicella-zoster virus, the same virus that causes chickenpox.^{3,4} The Centers for Disease Control and Prevention (CDC) and the National Institute of Health (NIH), National Institute of Neurological Disorders and Stroke (NINDS) cite the use of oral antivirals (acyclovir capsules/tablets/suspension [Zovirax, generics], famciclovir tablets [Famvir®, generics], and valacyclovir caplets [Valtrex®, generics]) 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® cream [prescribing information]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; January 2017.
2. Zovirax® ointment [prescribing information]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; January 2017.
3. Centers for Disease Control and Prevention – Shingles. Available at: <http://www.cdc.gov/shingles/about/prevention-treatment.html>. Updated July 2019. Accessed on June 12, 2020.
4. 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 2020. Accessed on June 12, 2020.