PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 07/26/2023

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Cigna National Formulary Coverage:

Overview

Acyclovir 5% cream (Zovirax, generic) is indicated for the treatment of **recurrent herpes labialis (cold sores)** in immunocompetent patients ≥ 12 years of age.[1]

Acyclovir 5% ointment (Zovirax, generics) is indicated for the following uses:[2]
- **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.

Zovirax® (acyclovir 5% cream –Bausch Health, generic)
Zovirax® (acyclovir 5% ointment – Bausch Health, generic)
is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

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

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 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] 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 (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 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 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 COVERED

Zovirax® (acyclovir 5% cream –Bausch Health, generic)
Zovirax® (acyclovir 5% ointment – Bausch Health, generic)
is(are) considered experimental, investigational, or unproven for ANY other use(s) including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

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.

REFERENCES

1. Zovirax® cream [prescribing information]. Bridgewater, NJ: Bausch Health; February 2021.
2. Zovirax® 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 18, 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	07/20/2022
Annual Revision	**Genital Herpes:** The patient cannot use a generic product due to a difference in dyes, fillers, and preservatives was changed to more specifically state differences in buffers, emollients, emulsifiers, and surfactants. **Limited Non-Life-Threatening Mucocutaneous Herpes Simplex Virus Infections:** The patient cannot use a generic product due to a difference in dyes, fillers, and preservatives was changed to more specifically state differences in buffers, emollients, emulsifiers, and surfactants.	07/26/2023

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