Prior Authorization
Topical Acyclovir Cream and Ointment

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**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.

**NPF Coverage Policy**

**Drugs Affected**

- Zovirax® (acyclovir 5% cream)
- Zovirax® (acyclovir 5% ointment)

Cigna covers topical acyclovir (Zovirax®) cream or ointment as medically necessary when the following criteria are met for FDA Indications or Other Uses with Supportive Evidence:

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.

**FDA Indication(s)**

I. Coverage of acyclovir 5% cream (Zovirax 5% cream, generics) is recommended in those who meet the following criterion:
1. **Herpes Labialis (Cold Sores).** Approve for 1 year if the individual meets both of the following criteria (A and B):
   
   A) Individual is ≥ 12 years of age; AND  
   B) Individual is immunocompetent.

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

1. **Genital Herpes.** Approve for 1 year if the individual 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 individual meets both of the following criteria (i and ii):
      
      i. Individual has tried generic acyclovir 5% ointment; AND  
      ii. Individual 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.

2. **Limited Non-Life-Threatening Mucocutaneous Herpes Simplex Virus Infections.** Approve for 1 year if the individual meets one of the following criteria (A and B):
   
   A) Individual is immunocompromised; AND  
   B) Individual meets one of the following criteria (i or ii):
      
      i. Generic acyclovir 5% ointment is requested; OR  
      ii. If brand Zovirax 5% ointment is requested, the individual meets both of the following criteria (a and b):
         
         a) Individual has tried generic acyclovir 5% ointment; AND  
         b) Individual 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 Covered**

Topical acyclovir (Zovirax®) cream or ointment is considered experimental, investigational or unproven for ANY other use including the following (this list may not be all inclusive):

1. **Shingles.** Shingle is a viral infection caused by the varicella-zoster virus, the same virus that causes chickenpox. 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.

**Background**

**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. 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.

**References**


### Last Revision Details

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<th>Annual revision</th>
<th>Policy name revised from “Zovirax (Topical) PA Policy” to “Topical Acyclovir Cream and Ointment PA Policy.” No criteria changes.</th>
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