Effective Date **11/1/2023**
Next Review Date… **11/1/2024**
Coverage Policy Number **IP0276**

Topical Antivirals

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Related Coverage Resources

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.

Overview

This policy supports medical necessity review for the following Topical Antiviral Products:

- **acyclovir** 5% cream
- **acyclovir** 5% ointment
- **Denavir®** (penciclovir) 1% cream
- **Xerese®** (acyclovir and hydrocortisone) 5%-1% cream
- **Zovirax®** (acyclovir) 5% cream and ointment

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Coverage varies across plans and requires the use of preferred products. Refer to the customer's benefit plan document for coverage details.

The products in the table below are considered medically necessary when the following are met:

Employer Group Non-Covered Products and Preferred Covered Alternatives:

Non-Covered Product	Criteria
acyclovir 5% cream	Individual meets the following criteria: 1. **Herpes Labialis (Cold Sores)**. There is documentation of **ALL** of the following (A, B, and C): A. Individual is 12 years of age or older B. Individual is immunocompetent C. There is documentation the individual has had an inadequate response, contraindication, or is intolerant to **TWO** of the following: i. acyclovir capsules (200mg), tablets (400 or 800mg), or oral suspension (200mg/5ml) ii. famciclovir tablets (125mg, 250mg, or 500mg) iii. valacyclovir tablets (500 or 1000mg)
acyclovir 5% ointment	Individual meets **ONE** of the following (1 or 2): 1. **Genital Herpes.** Individual meets **BOTH** of the following (A and B): A. Individual is 18 years of age or older B. There is documentation the individual has had an inadequate response, contraindication, or is intolerant to **TWO** of the following: i. acyclovir capsules (200mg), tablets (400 or 800mg), or oral suspension (200mg/5ml) ii. famciclovir tablets (125mg, 250mg, or 500mg) iii. valacyclovir tablets (500 or 1000mg) 2. **Mucocutaneous Herpes Simplex Virus infections**. Individual meets **ALL** of the following (A, B, and C): A. Individual is 18 years of age or older B. Individual is immunocompromised C. There is documentation the individual has had an inadequate response, contraindication, or is intolerant to **TWO** of the following: i. acyclovir capsules (200mg), tablets (400 or 800mg), or oral suspension (200mg/5ml) ii. famciclovir tablets (125mg, 250mg, or 500mg) iii. valacyclovir tablets (500 or 1000mg)
Denavir (penciclovir) 1% cream	**Standard /Performance/Value /Advantage /Cigna Total Savings** Individual meets **ALL** of the following criteria: 1. **Recurrent Herpes Labialis (Cold Sores)**. There is documentation of **BOTH** of the following (A and B): A. Individual is 12 years of age or older B. There is documentation the individual has had an inadequate response, contraindication, or is intolerant to **TWO** of the following: i. acyclovir capsules (200mg), tablets (400 or 800mg), or oral suspension (200mg/5ml) ii. famciclovir tablets (125mg, 250mg, or 500mg) iii. valacyclovir tablets (500 or 1000mg)
Xerese® (acyclovir and hydrocortisone) 5%-1% cream	Individual meets **ALL** of the following criteria: 1. **Recurrent Herpes Labialis (Cold Sores)**. There is documentation of **BOTH** of the following:

	A. Individual is 6 years of age or older B. There is documentation the individual has had an inadequate response, contraindication, or is intolerant to **TWO** of the following: i. acyclovir capsules (200mg), tablets (400 or 800mg), or oral suspension (200mg/5ml) ii. famciclovir tablets (125mg, 250mg, or 500mg) iii. valacyclovir tablets (500 or 1000mg)
Zovirax (acyclovir) 5% cream	Individual meets **ALL** of the following criteria: 1. **Herpes Labialis (Cold Sores)**. There is documentation of **ALL** of the following (A, B, and C): A. Individual is 12 years of age or older B. Individual is immunocompetent C. There is documentation the individual has had an inadequate response, contraindication, or is intolerant to **TWO** of the following: i. acyclovir capsules (200mg), tablets (400 or 800mg), or oral suspension (200mg/5ml) ii. famciclovir tablets (125mg, 250mg, or 500mg) iii. valacyclovir tablets (500 or 1000mg)
Zovirax (acyclovir) 5% ointment	Individual meets **ALL** of the following criteria: 1. **Genital Herpes**. Individual meets **BOTH** of the following (A, and B): A. Individual is 18 years of age and older B. There is documentation the individual has had an inadequate response, contraindication, or is intolerant to **TWO** of the following: i. acyclovir capsules (200mg), tablets (400 or 800mg), or oral suspension (200mg/5ml) ii. famciclovir tablets (125mg, 250mg, or 500mg) iii. valacyclovir tablets (500 or 1000mg) 2. **Mucocutaneous Herpes Simplex Virus Infections.** Individual meets **ALL** of the following (A, B, and C): A. Individual is 18 years of age and older B. Individual is immunocompromised C. There is documentation the individual has had an inadequate response, contraindication, or is intolerant to **TWO** of the following: i. acyclovir capsules (200mg), tablets (400 or 800mg), or oral suspension (200mg/5ml) ii. famciclovir tablets (125mg, 250mg, or 500mg) iii. valacyclovir tablets (500 or 1000mg)

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Topical Antiviral Products are considered medically necessary for continued use when initial criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration is up to 12 months.
Reauthorization approval duration is up to 12 months.

Conditions Not Covered

Any other use of topical antiviral agents is considered experimental, investigational or unproven, including the following (this list may not be all inclusive):

- Shingles (Herpes Zoster)

Background

OVERVIEW

Professional Societies/Organizations

National guidelines published by the CDC report that the topical antiviral agents offer minimal clinical benefit for genital herpes infections and should not be recommended over the oral antiviral agents (acyclovir, famciclovir, and valacyclovir).[6]

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.

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.
4. Xerese [prescribing information]. Bridgewater, NJ: Bausch Health US, LLC; August 2020.
5. Denavir [prescribing information]. Morgantown, WV: Mylan Pharmaceuticals; November 2018.
6. Centers for Disease Control and Prevention. Sexually Transmitted Infections Treatment Guidelines. MMWR. 2021 June 23;70(4):1-192. Available from: https://www.cdc.gov/std/treatment-guidelines/STI-Guidelines-2021.pdf. Accessed August 12, 2021.