

# Initial Prior Authorization

## Antiviral Topical

### Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name	Dosage Form
Denavir	penciclovir	all
Xerese	acyclovir / hydrocortisone	all
Zovirax	acyclovir	cream, ointment

### Indications

#### FDA-approved Indications

##### Denavir

Denavir is a deoxynucleoside analog HSV DNA polymerase inhibitor indicated for the treatment of recurrent herpes labialis (cold sores) in adults and children 12 years of age or older.

##### Xerese

Xerese, a combination of acyclovir, a herpes simplex virus deoxynucleoside analog DNA polymerase inhibitor, and hydrocortisone, a corticosteroid, is indicated for the early treatment of recurrent herpes labialis (cold sores) to reduce the likelihood of ulcerative cold sores and to shorten the lesion healing time in adults and children (6 years of age and older).

##### Zovirax Cream

Zovirax Cream is a herpes simplex virus (HSV) deoxynucleoside analogue DNA polymerase inhibitor indicated for the treatment of recurrent herpes labialis (cold sores) in immunocompetent adults and adolescents 12 years of age and older.

Reference number(s)
1492-A

## Zovirax Ointment

Zovirax Ointment 5% is indicated in the management of initial genital herpes and in limited non-life-threatening mucocutaneous HSV infections in immunocompromised patients.

## Coverage Criteria

### Genital Herpes, Mucocutaneous Herpes Simplex Virus (HSV)

Authorization may be granted when the requested drug is being prescribed for the management of initial genital herpes OR mucocutaneous herpes simplex virus (HSV) infection in an immunocompromised patient when the following criteria is met:

- The request is for Zovirax Ointment (acyclovir ointment).

### Recurrent Herpes Labialis (Cold Sores)

Authorization may be granted when the requested drug is being prescribed for the treatment of recurrent herpes labialis (cold sores) when ONE of the following criteria are met:

- The request is for Xerese (acyclovir/hydrocortisone) and the following criteria is met:
  - The patient is 6 years of age or older.
- The request is for Denavir (penciclovir) and the following criteria is met:
  - The patient is 12 years of age or older.
- The request is for Zovirax Cream (acyclovir cream) and ALL of the following criteria are met:
  - The patient is immunocompetent.
  - The patient is 12 years of age or older.

## Duration of Approval (DOA)

- 1492-A: DOA: 12 months

## References

1. Denavir [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc.; November 2018.
2. Xerese [package insert]. Bridgewater, NJ: Bausch Health US, LLC; August 2020.
3. Zovirax Cream [package insert]. Bridgewater, NJ: Bausch Health US, LLC; February 2021.
4. Zovirax Ointment [package insert]. Bridgewater, NJ: Bausch Health US, LLC; October 2020.
5. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed September 10, 2024.

Reference number(s)
1492-A

6. Lexicomp Online, Lexi Drugs Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed September 10, 2024.
7. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 09/10/2024).