

### acyclovir 5% ointment

#### Disclaimer

*Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.*

*Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.*

#### Summary

Acyclovir 5% ointment is a topical drug that is FDA approved for use in the treatment of herpes simplex virus. Acyclovir can be used in immunocompromised patients to shorten the clinical course of herpes virus infections or as preventative therapy to suppress the reactivation of an infection. Acyclovir can be used in pediatric and adult patients and is commercially available in multiple formulations. The most common side effect with topical Acyclovir includes skin irritation (pain, burning, or stinging) at the application site.

#### Definitions

"Herpes Simplex Virus (HSV)" is a contagious virus that causes herpes and can be transmitted from person to person through direct contact. Herpes can appear in various parts of the body, most commonly on the genitals or mouth. There are two types of the herpes simplex virus:

- HSV-1: primarily causes oral herpes - generally responsible for cold sores and fever blisters around the mouth and on the face
- HSV-2: primarily causes genital herpes outbreaks

"Immunocompromised" is a term that describes a person with a weakened immune system response such that he/she has an increased likelihood of contracting infections more frequently or of a greater

severity. Examples of medical conditions that are considered to cause an immunocompromised status include autoimmune disorders (rheumatoid arthritis, multiple sclerosis, or lupus), HIV, cancer (those with active disease and/or receiving chemotherapy or radiation treatments), post-transplant, or pregnancy.

### Medical Necessity Criteria for Initial Authorization

The Plan considers acyclovir 5% ointment medically necessary when ALL of the following criteria are met:

1. The member has ONE of the following as a documented diagnosis:
  - a. Initial treatment of genital herpes; or
  - b. Non-life-threatening herpes simplex virus infection in an immunocompromised patient at a site where skin and mucous membranes meet
2. The member has experienced failure, intolerance, or contraindication to TWO of the following oral antiviral agents:
  - a. acyclovir (Zovirax)
  - b. famciclovir (Famvir)
  - c. valacyclovir (Valtrex)

If the above prior authorization criteria are met, acyclovir 5% ointment will be approved for 6 months.

### Experimental or Investigational / Not Medically Necessary

Acyclovir 5% ointment for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven.

### References

1. Zovirax 5% ointment [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals, LLC; Jan 2017.
2. Albrecht MA. Treatment of genital herpes simplex virus. Up to Date® Last Updated June 2021. Accessed Sept 2021. Available from: <http://www.uptodate.com>
3. Klein RS. Treatment of herpes simplex virus type 1 infection in immunocompetent patients. Up to Date®: Last updated September 2017. Accessed October 2017. Available from: <http://www.uptodate.com>.
4. Workowski KA, Bolan GA; Centers for Disease Control and Prevention. Sexually transmitted diseases treatment guidelines. MMWR Recomm Rep. 2015;64(RR-03):1–137.

### Clinical Guideline Revision / History Information

Original Date: 10/14/2021 <u>Reviewed/Revised:</u> 12/01/2021
------------------------------------------------------------------