acyclovir 5% ointment (Zovirax)

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 an approved medication for treating herpes simplex virus infections. It is a topical antiviral treatment that can be used by both children and adults. It is particularly beneficial for immunocompromised individuals as it helps reduce the duration of herpes outbreaks and can be used as a preventive measure against reactivation of the virus.

Acyclovir is available in different forms, such as tablets, capsules, suspension, injection, as well as topical formulations like ointments and creams. The choice of formulation depends on factors like the patient's condition, location of the infection, age, and other existing health conditions.

When using Acyclovir ointment topically, some common side effects may occur. These include local skin irritation, which can manifest as pain, burning, or stinging at the site of application. However, the

absorption of Acyclovir into the bloodstream through topical use is minimal, although it may occur in patients with compromised skin barriers.

It is important to note that while Acyclovir 5% ointment is FDA-approved for the initial treatment of genital herpes, the US Centers for Disease Control and Prevention (CDC) does not recommend this specific formulation for managing genital herpes due to limited clinical benefits.

Definitions

"Herpes Simplex Virus (HSV)" is a highly infectious virus causing herpes, which can be transferred from one person to another via direct contact. Herpes infections predominantly manifest on the genitals or the oral region. The herpes simplex virus is categorized into two types:

- HSV-1: This variant is the primary cause of oral herpes, typically responsible for cold sores and fever blisters around the mouth and on the face. However, it can also cause genital herpes through oral-genital contact.
- HSV-2: This variant is mainly associated with genital herpes, but it can also cause oral herpes through genital-oral contact.

"**Immunocompromised**"describes individuals with a weakened immune response, making them susceptible to infections, which may be more frequent or severe compared to immunocompetent individuals. Patients can become immunocompromised due to a variety of conditions such as autoimmune disorders (e.g., rheumatoid arthritis, multiple sclerosis, lupus), HIV, active cancer or those undergoing chemotherapy or radiation, organ transplant recipients, the elderly, and during pregnancy. Certain medications, like corticosteroids and other immunosuppressive drugs, can also render a person immunocompromised.

Medical Necessity Criteria for Authorization

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

1. The member has a documented diagnosis of **ONE** of the following conditions:
    a. Genital herpes, and the requested medication is being used in the treatment of the initial episode or recurrent outbreaks***; or***
    b. Non-life-threatening, nongenital, mucocutaneous herpes simplex virus (HSV-1 or HSV-2) infections in immunocompromised adults***; AND***
2. The member is unable to use, or has tried and failed **TWO** of the following oral antiviral agents:

a. acyclovir (Zovirax)***; and/or***
b. famciclovir (Famvir)***; and/or***
c. valacyclovir (Valtrex).

<u>If the above prior authorization criteria are met, acyclovir 5% ointment will be approved for up to 6 months.</u>

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

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5. Workowski KA, Bachmann LH, Chan PA, et al. Sexually transmitted infections treatment guidelines, 2021. MMWR Recomm Rep. 2021;70(4):1-187. doi:10.15585/mmwr.rr7004a1
6. Zovirax ointment (acyclovir) [prescribing information]. Bridgewater, NJ: Bausch Health US, LLC; October 2020.

Clinical Guideline Revision / History Information

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