Oscar Clinical Guideline: Verkazia (cyclosporine ophthalmic emulsion) 0.1% (PG236, Ver. 2)

Verkazia (cyclosporine ophthalmic emulsion) 0.1%

Summary

Vernal keratoconjunctivitis (VKC) is a chronic, seasonal, allergic eye condition primarily affecting children and young adults. It is characterized by intense itching, photophobia (abnormal light sensitivity), mucous discharge, and the formation of giant papillae on the upper tarsal conjunctiva. VKC can lead to corneal complications and vision impairment if left untreated.

First-line treatments include artificial tears, cold compresses, and topical antihistamines/mast cell stabilizers (e.g., olopatadine, alcaftadine, ketotifen fumarate, azelastine hydrochloride, epinastine, and pemirolast potassium, or combinations use of separate topical mast cell stabilizers and topical antihistamines). For moderate-to-severe cases, oral antihistamines may be added or topical corticosteroids may be used for short-term management of acute symptoms. In the event of topical corticosteroid failure, a topical calcineurin inhibitors is trialed as a corticosteroid-sparing therapy, to prevent long-term topical steroid side effects (i.e., glaucoma, cataracts, secondary infections). Verkazia (cyclosporine ophthalmic emulsion 0.1%) is a calcineurin inhibitor immunosuppressant indicated for the treatment of VKC in those 4 years and older. It offers a steroid-sparing option for long-term management of moderate to severe VKC, with demonstrated efficacy in reducing signs and symptoms of the condition.

Definitions

"Giant papillae" refers to large, raised, cobblestone-like projections on the upper tarsal conjunctiva, typically greater than 1 mm in diameter, which are a hallmark sign of VKC.

"Moderate to severe VKC" refers to cases of vernal keratoconjunctivitis characterized by persistent symptoms, significant discomfort, and potential for corneal involvement, often requiring more aggressive treatment than mild cases.

"Vernal keratoconjunctivitis (VKC)" is a chronic, bilateral, and recurrent allergic inflammatory disorder of the ocular surface, primarily affecting children and young adults, characterized by intense itching, photophobia, mucous discharge, and the presence of giant papillae on the upper tarsal conjunctiva.

Medical Necessity Criteria for Initial Authorization

The Plan considers Verkazia (cyclosporine ophthalmic emulsion) 0.1% medically necessary when ALL of the following criteria are met:

1. Prescribed by or in consultation with an ophthalmologist or optometrist; *AND*
2. The member is 4 years of age or older; *AND*
3. The member has a diagnosis of moderate to severe vernal keratoconjunctivitis; *AND*
4. The member is unable to use, or has tried and failed ONE (1) of the following:
    a. Anophthalmic antihistamine (e.g., epinastine); *or*
    b. Anophthalmic mast cell stabilizer (e.g., cromolyn); *or*
    c. An ophthalmic dual-action antihistamine/mast cell stabilizer (e.g., olopatadine, ketotifen); *AND*
5. The member has had an inadequate response to short-term use of ophthalmic/topical corticosteroids (e.g., loteprednol, prednisolone), or has a contraindication to corticosteroid use.

If the above prior authorization criteria are met, the requested product will be authorized for up to 12-months.

Medical Necessity Criteria for Reauthorization

Reauthorization for up to 12-months will be granted if the member has recent (within the last 3-months) clinical chart documentation demonstrating ALL of the following criteria:

1. The member continues to meet applicable Initial Authorization approval criteria; *AND*
2. The member has documentation of positive clinical response to therapy as evidenced by improvement in signs and symptoms of VKC (e.g., decreased itching, tearing, photophobia, mucous discharge).

Experimental or Investigational / Not Medically Necessary

Verkazia (cyclosporine ophthalmic emulsion) 0.1% for any other indication or use is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven. Non-covered indications include, but are not limited to, the following:

- Treatment of allergic conjunctivitis other than vernal keratoconjunctivitis. While there is some favorable data to support the use, most studies offer conflicting data to support the safety and efficacy of Verkazia (cyclosporine ophthalmic emulsion) for allergic conjunctivitis. There is no high quality data comparing Verkazia (cyclosporine ophthalmic emulsion) to the standard of care, topical corticosteroids in the setting of refractory disease.
- Treatment of dry eye disease. While cyclosporine ophthalmic emulsion (Restatis) is used for dry eyes, Verkazia (cyclosporine ophthalmic emulsion) is only approved for the use of VKC.
- Treatment of atopic keratoconjunctivitis (AKC). There is not enough high quality data to support the safety and efficacy of Verkazia (cyclosporine ophthalmic emulsion) for the management of AKC.
- Use in members under 4 years of age. Verkazia (cyclosporine ophthalmic emulsion) has only been studied in those 4 years and older. There is not enough data support the safety and efficacy of Verkazia (cyclosporine ophthalmic emulsion) for the management of those less than 4 years of age.

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