

Verkazia (cyclosporine ophthalmic emulsion) 0.1%

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

Vernal keratoconjunctivitis (VKC) is a chronic, seasonal, allergic eye condition primarily affecting children and young adults. It is characterized by intense itching, photophobia, 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. For moderate to severe cases, topical corticosteroids may be used for short-term management of acute symptoms. Verkazia (cyclosporine ophthalmic emulsion 0.1%) is a calcineurin inhibitor immunosuppressant indicated for the treatment of VKC in patients 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 **BOTH** of the following:
 - a. At least **ONE** ophthalmic antihistamine (e.g., epinastine) **OR** ophthalmic mast cell stabilizer (e.g., cromolyn)
 - b. At least **ONE** ophthalmic dual-action antihistamine/mast cell stabilizer (e.g., olopatadine, ketotifen)
5. The member has had an inadequate response to short-term use of ophthalmic 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 12-months.

Medical Necessity Criteria for Reauthorization

Reauthorization for 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 **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.
- Treatment of dry eye disease.
- Treatment of atopic keratoconjunctivitis.
- Use in members under 4 years of age.

References

1. Lambiase A, Leonardi A, Sacchetti M, Deligianni V, Sposato S, Bonini S. Topical cyclosporine prevents seasonal recurrences of vernal keratoconjunctivitis in a randomized, double-masked, controlled 2-year study. *J Allergy Clin Immunol*. 2011 Oct;128(4):896-897.e9. doi: 10.1016/j.jaci.2011.07.004. Epub 2011 Aug 25. PMID: 21868078.
2. Leonardi A, Doan S, Amrane M, Ismail D, Montero J, Németh J, Aragona P, Bremond-Gignac D; VEKTIS Study Group. A Randomized, Controlled Trial of Cyclosporine A Cationic Emulsion in Pediatric Vernal Keratoconjunctivitis: The VEKTIS Study. *Ophthalmology*. 2019 May;126(5):671-681. doi: 10.1016/j.ophtha.2018.12.027. Epub 2018 Dec 27. PMID: 30593775.
3. Ozcan AA, Ersoz TR, Dulger E. Management of severe allergic conjunctivitis with topical cyclosporin a 0.05% eyedrops. *Cornea*. 2007 Oct;26(9):1035-8. doi: 10.1097/ICO.0b013e31812dfab3. PMID: 17893529.
4. Verkazia (cyclosporine) [prescribing information]. Emeryville, CA: Santen Incorporated; June 2022.
5. Vichyanond P, Kosrirukvongs P. Use of cyclosporine A and tacrolimus in treatment of vernal keratoconjunctivitis. *Curr Allergy Asthma Rep*. 2013 Jun;13(3):308-14. doi: 10.1007/s11882-013-0345-0. PMID: 23625179.

Clinical Guideline Revision / History Information

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