

## 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.*

Verkazia (cyclosporine ophthalmic emulsion) 0.1%	1
Summary	2
Definitions	2
Clinical Indications	3
Medical Necessity Criteria for Clinical Review	3
General Medical Necessity Criteria	3
Medical Necessity Criteria for Initial Clinical Review	3
Initial Indication-Specific Criteria	3
Vernal Keratoconjunctivitis	3
Medical Necessity Criteria for Subsequent Clinical Review	3
Subsequent Indication-Specific Criteria	3
Vernal Keratoconjunctivitis	3
Experimental / Investigational, unproven	4
References	4
Clinical Guideline Revision / History Information	5

## 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 inhibitor 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

“Documentation” refers to written information, including but not limited to:

- Up-to-date chart notes, relevant test results, and/or relevant imaging reports to support diagnoses; or
- Prescription claims records, and/or prescription receipts to support prior trials of formulary alternatives.

“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.

“[s]” indicates state mandates may apply.

## Clinical Indications

### Medical Necessity Criteria for Clinical Review

#### General Medical Necessity Criteria

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. Verkazia (cyclosporine ophthalmic emulsion) 0.1% is being prescribed at a dose and frequency that is within FDA approved labeling; *AND*
4. The member meets the applicable [Medical Necessity Criteria for Initial Clinical Review](#) or [Subsequent Clinical Review](#) listed below.

### Medical Necessity Criteria for Initial Clinical Review

#### Initial Indication-Specific Criteria

##### Vernal Keratoconjunctivitis

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

5. The member meets the above [General Medical Necessity Criteria](#); *AND*
6. The member has a diagnosis of moderate to severe vernal keratoconjunctivitis; *AND*
7. The member is unable to use, or has tried and failed ONE (1) of the following<sup>[s]</sup>:
  - a. Ophthalmic antihistamine (e.g., epinastine); *or*
  - b. Ophthalmic mast cell stabilizer (e.g., cromolyn); *or*
  - c. Ophthalmic dual-action antihistamine/mast cell stabilizer (e.g., olopatadine, ketotifen); *AND*
8. 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<sup>[s]</sup>.

If the above prior authorization criteria are met, the requested product will be authorized for up to 12-months.<sup>[s]</sup>

#### *Continued Care*

### Medical Necessity Criteria for Subsequent Clinical Review

#### Subsequent Indication-Specific Criteria

##### Vernal Keratoconjunctivitis

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

1. The member meets the above applicable [General Medical Necessity Criteria](#) and/or [Initial Clinical Review](#); *AND*
2. The member has documentation of a positive clinical response to therapy as evidenced by improvement in signs and symptoms of VKC (e.g., decreased itching, tearing, photophobia, mucous discharge).

If the above reauthorization criteria are met, the requested product will be authorized for up to 12-months.<sup>[s]</sup>

#### [Experimental / Investigational, unproven<sup>\[s\]</sup>](#)

Verkazia (cyclosporine ophthalmic emulsion) 0.1% for any other indication or use is considered 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 to support the safety and efficacy of Verkazia (cyclosporine ophthalmic emulsion) for the management of those less than 4 years of age.

#### [References](#)

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#### Clinical Guideline Revision / History Information

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