

PRIOR AUTHORIZATION POLICY

POLICY: Ophthalmology – Verkazia Prior Authorization Policy

- Verkazia® (cyclosporine 0.1% ophthalmic emulsion – Santen)

REVIEW DATE: 02/09/2022; selected revision 05/04/2022

OVERVIEW

Verkazia, a calcineurin inhibitor immunosuppressant, is indicated for the treatment of **vernal keratoconjunctivitis** in patients \geq 4 years of age.¹

Guidelines

Verkazia is not addressed in guidelines. However, ophthalmic cyclosporine products (in strengths of 0.05% and 2%) are discussed for the treatment of vernal keratoconjunctivitis in the American Academy of Ophthalmology Conjunctivitis Preferred Practice Pattern recommendations (2018).² Commercially available 0.05% ophthalmic cyclosporine has demonstrated efficacy with more frequent dosing for the treatment of vernal conjunctivitis. It has been shown to reduce signs and symptoms, prevent seasonal recurrences, and may reduce use of topical steroids. Besides cyclosporine, other medications recommended for maintenance of vernal keratoconjunctivitis include ocular lubricants, antihistamines (oral and ophthalmic), and ophthalmic mast-cell stabilizers. Ophthalmic corticosteroids are reserved for acute exacerbations.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Verkazia. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Verkazia as well as the monitoring required for adverse events and long-term efficacy, approval requires Verkazia to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Verkazia is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Vernal Keratoconjunctivitis.** Approve for 1 year if the patient meets the following criteria (A, B, C, and D):
 - A) Patient is \geq 4 years of age; AND
 - B) According to the prescriber, the patient has moderate to severe vernal keratoconjunctivitis; AND
 - C) Patient meets one of the following (i or ii):
 - i. Patient has tried two single-action ophthalmic medications (i.e., ophthalmic mast-cell stabilizers or ophthalmic antihistamines) for the maintenance treatment of vernal keratoconjunctivitis; OR

Note: Examples of single-action ophthalmic medications for the maintenance treatment of vernal keratoconjunctivitis include ophthalmic mast-cell stabilizers (e.g., cromolyn ophthalmic
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solution, Alomide ophthalmic solution]) and ophthalmic antihistamines (e.g., Zerviate [cetirizine solution]).

- ii. Patient has tried one dual-action ophthalmic mast-cell stabilizer/antihistamine product for the maintenance treatment of vernal keratoconjunctivitis; AND

Note: Examples of dual-action ophthalmic mast-cell stabilizer/antihistamine products include azelastine ophthalmic solution, beoptastine ophthalmic solution, epinastine ophthalmic solution, ketotifen ophthalmic solution, Lastacaft, and olopatadine ophthalmic solution.

Note: An exception to the requirement for a trial of two single-action ophthalmic medications (i.e., ophthalmic mast-cell stabilizers or ophthalmic antihistamines) or one dual-action ophthalmic mast-cell stabilizer/antihistamine product for the maintenance treatment of vernal keratoconjunctivitis can be made if the patient has already tried at least one ophthalmic cyclosporine product (e.g., Cequa [cyclosporine 0.09% ophthalmic solution], Restasis [cyclosporine 0.05% ophthalmic emulsion]) other than the requested medication.

- D) The medication is prescribed by or in consultation with an optometrist or ophthalmologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Verkazia is not recommended in the following situations:

- 1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

- 1. Verkazia® ophthalmic emulsion [prescribing information]. Emeryville, CA: Santen; June 2021.
- 2. Varu D, Rhee M, Akpek E, et al. American Academy of Ophthalmology Preferred Practice Pattern Cornea and External Disease Panel. Conjunctivitis Preferred Practice Pattern®. *Ophthalmology*. 2019;126:P94-P169.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	02/09/2022
Selected Revision	Vernal Keratoconjunctivitis: The requirement for a trial of one other ophthalmic medication for the maintenance treatment of vernal keratoconjunctivitis was revised to require two single-action ophthalmic medications (i.e., ophthalmic mast-cell stabilizers or ophthalmic antihistamines) or one dual-action ophthalmic mast-cell stabilizer/antihistamine product. The Notes in the policy were revised accordingly.	05/04/2022