

PRIOR AUTHORIZATION POLICY

- POLICY:** Ophthalmology – Verkazia Prior Authorization Policy
- Verkazia[®] (cyclosporine 0.1% ophthalmic emulsion – Santen)

REVIEW DATE: 01/24/2024

OVERVIEW

Verkazia, a calcineurin inhibitor immunosuppressant, is indicated for the treatment of **vernal keratoconjunctivitis** (VKC) in patients ≥ 4 years of age.¹

Disease Overview

VKC, a type of allergic conjunctivitis, is a recurrent, bilateral allergic inflammation of the conjunctiva and the superficial cornea.^{3,4} VKC is more common in males and is more prevalent in hot, dry climates and in tropical and sub-tropical countries.⁴ Common symptoms include itching, photophobia, burning, foreign body sensation, mucoid discharge, and tearing. It is thought that both immunoglobulin E (IgE)-mediated and cell-mediated immune mechanisms are responsible for exacerbations.

Treatment of VKC depends on the extent and severity of the disease at the time of presentation.^{3,4} First-line treatment are lubricating therapies, e.g., preservative-free artificial tears, gels, or ointments. Treatment of moderate cases includes use of ophthalmic mast cell stabilizers (e.g., cromolyn, nedocromil, lodoxamide) and ophthalmic antihistamines. Dual-action ophthalmic products that contain a mast cell stabilizer and an antihistamine are preferred for moderate to severe cases; these agents have a quick onset of action. Ophthalmic nonsteroidal anti-inflammatory agents and ophthalmic corticosteroids have also shown beneficial effects. Intraocular pressure should be monitored in patients receiving ophthalmic corticosteroids. Steroid-sparing agents such as topical immunomodulators (e.g., cyclosporine 0.05% to 2%) are safe alternatives for patients with recurrent episodes.

Guidelines

Verkazia is not addressed in guidelines. The American Academy of Ophthalmology Conjunctivitis Preferred Practice Pattern (PPP) recommendations (2018) note that ophthalmic cyclosporine products have shown to reduce signs and symptoms compared with placebo in patients with VKC.⁴ With regards to vernal/atopic conjunctivitis, the PPP notes ophthalmic mast cell stabilizers and ophthalmic antihistamines are efficacious. In addition, ophthalmic corticosteroids are usually necessary to control signs and symptoms of acute exacerbations of vernal/atopic conjunctivitis.

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.

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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 (A, B, C, and D):
 - A) Patient is ≥ 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 solution, Alomide (lodoxamide ophthalmic solution)) and ophthalmic antihistamines (e.g., Zerviate [cetirizine ophthalmic 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, bepotastine ophthalmic solution, epinastine 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], Vevye [cyclosporine 0.1% ophthalmic solution]) 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.
3. Burrow MK, Patel BC. Keratoconjunctivitis. [Updated 2023 Aug 7]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK542279/>. Accessed on January 23, 2024.
4. Kaur K, Gurnani B. Vernal Keratoconjunctivitis. [Updated 2023 Jun 11]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK576433/>. Accessed on January 23, 2024.

