MEDICAL MUTUAL®

Drug Policy

Policy:	Verkazia® (cyclosporine 0.1% ophthalmic emulsion – Santen)	Annual Review Date: 03/20/2025 Last Revised Date: 03/20/2025

OVERVIEW

Verkazia, a calcineurin inhibitor immunosuppressant, is indicated for the treatment of **vernal keratoconjunctivitis** (VKC) in children and adults.[1] Efficacy and safety of Verkazia have been established in pediatric patients ≥ 4 years of age.

POLICY STATEMENT

This policy involves the use of Verkazia. Prior authorization is recommended for pharmacy benefit coverage of Verkazia. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

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, initial approval requires Verkazia be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

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

1. <u>Vernal Keratoconjunctivitis</u>

Criteria. *Patient must meet the following criteria (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 <u>or</u> 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
  <u>Note</u>: Examples of single-action ophthalmic medications for the maintenance treatment of vernal keratoconjunctivitis include ophthalmic mast-cell stabilizers (e.g., cromolyn ophthalmic solution, Alomide 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, beoptastine ophthalmic solution, epinastine ophthalmic solution, ketotifen ophthalmic solution, Lastacaft, and olopatadine ophthalmic solution; AND
Note: An exception to this 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], cyclosporine 0.05A% ophthalmic emulsion [Restasis, generic], Verye [cyclosporine 0.1% ophthalmic solution]) other than the requested medication.

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

Initial Approval/ Extended Approval.
A) *Initial Approval:* 365 days
B) *Extended Approval:* 365 days

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Verkazia has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

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

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Verkazia® ophthalmic emulsion [prescribing information]. Emeryville, CA: Santen; June 2022.

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 13, 2025.
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 13, 2025.