PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 01/29/2025

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

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.

Disease Overview

VKC, a type of allergic conjunctivitis, is a recurrent, bilateral allergic inflammation of the conjunctiva and the superficial cornea.[2-4] 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.[2] 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.

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

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

1. **Vernal Keratoconjunctivitis.** Approve for 1 year if the patient meets ALL of 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 (alfcatadine ophthalmic solution), and olopatadine ophthalmic solution; AND

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], cyclosporine 0.05% ophthalmic emulsion [Restasis, generic], 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 COVERED

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

is(are) considered experimental, investigational or unproven for ANY other use(s) including the following; criteria will be updated as new published data are available

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.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	01/24/2024
Annual Revision	No criteria changes.	01/29/2025