PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 01/18/2023

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** in patients ≥ 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.

- **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 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 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 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.

     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 COVERED

- **Verkazia® (cyclosporine 0.1% ophthalmic emulsion – Santen) is(are) considered experimental, investigational or unproven for ANY other use(s)**; **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.

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
Annual Revision	No criteria changes.	01/18/2023