

Verkazia[®] (cyclosporine ophthalmic emulsion)

Policy # 00802

Original Effective Date: 08/08/2022

Current Effective Date: 08/01/2026

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Investigational or experimental services are not covered. This includes any drug, device, procedure, or service provided under the investigational arm of a clinical trial or clinical study. These services are excluded from coverage under benefits.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider Verkazia^{®†} (cyclosporine ophthalmic emulsion) to be **eligible for coverage**** when the patient selection criteria are met.

Patient Selection Criteria

Coverage eligibility for Verkazia (cyclosporine ophthalmic emulsion) will be considered when the following criteria are met:

- Patient has a diagnosis of moderate to severe vernal keratoconjunctivitis; AND
- Patient is greater than or equal to 4 years of age and less than or equal to 21 years of age; AND

*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*

- Patient meets ONE of the following:
 - Patient has tried ONE single-action ophthalmic medication (i.e., mast-cell stabilizer or ophthalmic antihistamine) for the maintenance treatment of vernal keratoconjunctivitis unless there is clinical evidence or patient history that suggests the use of single-action ophthalmic medications will be ineffective or cause an adverse reaction to the patient. Examples of single-action ophthalmic medications include cromolyn ophthalmic solution, Alomide^{®†} (lodoxamide ophthalmic solution), and Zerviate^{TM†} (cetirizine ophthalmic solution); OR
 - Patient has tried at least ONE dual-action mast-cell stabilizer/antihistamine ophthalmic medication for the maintenance treatment of vernal keratoconjunctivitis unless there is clinical evidence or patient history that suggests the use of dual-action ophthalmic medications will be ineffective or cause an adverse reaction to the patient. Examples of dual-action ophthalmic products for the maintenance treatment of vernal keratoconjunctivitis include olopatadine 0.1%, 0.2% drops, azelastine 0.05% drops, epinastine 0.05% drops, bepotastine 1.5% drops, and ketotifen 0.025% drops.

*(Note: These specific patient selection criteria are additional Company requirements for coverage eligibility and will be denied as not medically necessary** if not met).*

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Note: A previous trial of one ophthalmic cyclosporine product (e.g., Cequa [cyclosporine 0.09% ophthalmic solution], Restasis [cyclosporine 0.05% ophthalmic emulsion]) other than the requested drug also counts as a trial of one agent for vernal keratoconjunctivitis.

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Verkazia (cyclosporine ophthalmic emulsion) in patients younger than 4 years of age or older than 21 years of age or who have not tried and failed at least one alternative treatment for the condition to be **not medically necessary**.**

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of Verkazia (cyclosporine ophthalmic emulsion) for any indication other than moderate to severe vernal keratoconjunctivitis to be **investigational**.*

Background/Overview

Verkazia is an ophthalmic emulsion formulation of cyclosporine, a calcineurin inhibitor immunosuppressant, and is indicated for the treatment of vernal keratoconjunctivitis. It is supplied in single-dose vials which should be gently shaken and administered 4 times daily into each affected eye. Additionally, contact lenses should be removed prior to administration and can be reinserted 15 minutes after administration. Treatment can be discontinued after signs and symptoms are resolved and can be reinitiated if there is a recurrence.

Vernal keratoconjunctivitis (VKC) is a relatively rare ocular allergy that affects the ocular surface and causes itching and irritation. It primarily affects pediatric patients with males being more commonly affected than females. Treatment includes avoidance of triggers such as wind, heat, salt water, sunlight, and known aeroallergens in addition to avoidance of eye rubbing and administration of artificial tears and cool compresses. In addition to these non-pharmacologic treatments, patients should be started on a topical antihistamine or mast cell stabilizer or a dual-acting product that acts as an antihistamine and mast cell stabilizer. Topical ophthalmic cyclosporine products are also included in guidelines for the treatment of VKC, although guidelines have not yet been updated to include Verkazia. Additionally, ophthalmic corticosteroids may be used for acute exacerbations. Typically, treatment can be continued throughout the affected season and then discontinued until symptoms recur.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Verkazia was approved in June 2021 for the treatment of vernal keratoconjunctivitis in children and adults.

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Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

The safety and efficacy of Verkazia for the treatment of vernal keratoconjunctivitis (VKC) were evaluated in two randomized, multi-center, double-masked, vehicle-controlled clinical trials (VEKTIS and NOVATIVE).

In the VEKTIS study, patients with severe VKC were randomized to four times daily Verkazia 1 mg/mL or two times daily Verkazia 1 mg/mL or vehicle for the first 4 months. Similarly, in the NOVATIVE study, patients with moderate to severe VKC were randomized to four times daily Verkazia 1 mg/mL or four times daily cyclosporine ophthalmic emulsion 0.5 mg/mL or vehicle for the first month. In both studies, patients randomized to the vehicle group were switched to an active treatment group after the initial period. VEKTIS was a 12 month study and NOVATIVE was a 4 month study.

A total of 168 and 118 patients were enrolled in the VEKTIS and NOVATIVE studies for the efficacy analyses, respectively. Patients' ages ranged from 4 through 17 years in VEKTIS and 4 through 21 years in NOVATIVE, with most patients being between 4 and 11 years of age and male. Most of the patients had both limbal and tarsal forms of VKC. In both studies, patients had experienced VKC for a mean of 3 years prior to enrollment and all patients had a history of at least one recurrence of VKC in the year prior to study entry.

In the VEKTIS study, key efficacy evaluation was based on the change in corneal fluorescein staining (CFS) score and in itching score over 4 months. At month 4, patients in the Verkazia four times daily group (n=56) experienced a decrease of 2.3 points in the mean CFS score compared to a decrease of 1.2 points in the vehicle group (n=58). Similarly, patients in the Verkazia four times daily group experienced a decrease of 44.1 points in itching score compared to a decrease of 25.4 points in the vehicle group.

Analysis of the CFS score and itching score at Month 1 of the efficacy evaluation period in the NOVATIVE study also provided supporting evidence.

References

1. Verkazia [package insert]. Santen Incorporated. Emeryville, CA. Updated July 2021.
2. Vernal Keratoconjunctivitis. UpToDate. Updated February 2022.
3. Verkazia Prior Authorization Policy. Express Scripts. Updated May 2022.

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07/07/2022 Medical Policy Committee review

07/13/2022 Medical Policy Implementation Committee approval. New policy.

07/06/2023 Medical Policy Committee review

07/12/2023 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

07/02/2024 Medical Policy Committee review

07/10/2024 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

07/03/2025 Medical Policy Committee review

07/09/2025 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

07/21/2026 Pre Pharmacy & Therapeutics Committee review.

07/22/2026 Pharmacy & Therapeutics Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 07/2027

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 1. Consultation with technology evaluation center(s);
 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. Reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and

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- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient’s health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

NOTICE: If an authorization for an ongoing course of treatment has been provided to a member and the member changes from one health plan to another health plan (e.g., a member moves from carrier A to Louisiana Blue), Louisiana Blue may honor the previous health plan’s authorization for the same service under the same type of in-network benefit for a 90-day transition period. Documentation of the authorization for the ongoing course of treatment from the previous health plan must be provided to us by the member or their provider and the services provided for the course of treatment must otherwise be a covered service under the Louisiana Blue health plan. This provision does not apply to medications covered under the plan’s pharmacy benefit.