BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINE

VERKAZIA® (cyclosporine) ophthalmic emulsion Generic Equivalent (if available)

This Pharmacy Coverage Guideline (PCG):
- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively "Service") is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider's judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member's benefit plan; and
- Is subject to change as new information becomes available.

Scope
- This PCG applies to Commercial and/or Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance
- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The "Criteria" section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member's benefit plan.
- The "Description" section describes the Service.
- The "Definition" section defines certain words, terms or items within the policy and may include tables and charts.
- The "Resources" section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require prior authorization is available at www.azblue.com/pharmacy. You must fully complete the request form and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

Medical Necessity Requirements for VERKAZIA (cyclosporine) ophthalmic emulsion

Criteria for Initial Therapy:

Prescriber Qualifications
- Prescribed by an Ophthalmologist or Optometrist, or in consultation with one

Indication
- Diagnosis of active, moderate to severe bilateral vernal keratoconjunctivitis (VKC) with severe keratitis

Age Requirement
- 4 years of age or older

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Baseline Clinical Evaluation

- **ONE** of the following:
  - Seasonal form: Provider must submit evidence of seasonality in the spring
  - Continuous form: Provider must submit evidence of continuous nature of the disease
- History of at least one recurrence of active, moderate to severe vernal keratoconjunctivitis in the past year
- At least **TWO** of the following signs in at least one eye:
  - Giant papillae with diameter greater than or equal to 1 mm on upper tarsal conjunctiva
  - Superficial keratitis
  - Conjunctival and episcleral hyperemia
  - Corneal shield ulcers
  - Ptosis
  - Blepharospasm
- At least **TWO** of the following ocular symptoms in the same eye:
  - Burning/stinging
  - Tearing
  - Itching
  - Pain
  - Sticky eyelids
  - Foreign body sensation
  - Thick mucus discharge
  - Blurred vision
  - Photophobia

Alternative Therapies

- Failure, contraindication, or intolerance to **ALL** the following:
  - **ONE** of the following dual acting topical mast cell stabilizer/antihistamine agent (used with or without oral non sedating antihistamine):
    1. Olopatadine (Pataday or generic)
    2. Ketotifen (Zaditor or generic)
    3. Azelastine
    4. Epinastine (Elestat or generic)
  - **ONE** of the following topical mast cell stabilizer (used with or without oral non sedating antihistamine):
    1. Cromolyn
    2. Alocril (nedocromil)
    3. Alomide (lodoxamide)
  - Topical cyclosporine 0.05 percent emulsion (Restasis or generic)

Brand Specific Criteria

- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note:** Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

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Safety

- No concomitant use with another ophthalmic cyclosporine agent (e.g., Cequa, Restasis, Vevye)
- Does not have any of the following:
  - Ocular anomaly other than VKC interfering with ocular surface (e.g., trauma, post radiation keratitis, severe blepharitis, rosacea, corneal ulcer, etc.)
  - Active herpes keratitis or history of ocular herpes or active ocular herpes
  - Active herpes
  - Any other active ocular infection (viral, bacterial, fungal, protozoal)
  - Ocular surgery within prior 6 months
  - Presence or history of severe systemic allergy

Documentation Requirements

- A completed request form must be submitted including:
  - Chart notes
  - Lab results (include all related lab values from above criteria)
  - Supporting clinical documentation

Initial Therapy Criteria Approval Duration

- 6 months OR end of plan year

Criteria for Continuation of Therapy (renewal therapy):

Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy

Prescriber Qualifications

- Continues to be seen by a physician specializing in or is in consultation with an Ophthalmologist or Optometrist

Clinical Response

- **THREE** of the following:
  - Reduced need for topical corticosteroid rescue medication over baseline
  - Reduction in corneal ulcerations over baseline
  - Reduction in keratitis over baseline
  - Best corrected distance visual acuity (BCDVA) has improved or stabilized
  - Marked improvement in itching or mucus discharge or complete resolution of symptoms
- For continuous VKC indication, provider must submit evidence of continuous nature of the disease

Adherence

- Adherence to the prescribed therapy regimen has been documented

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Safety

- No concomitant use with another ophthalmic cyclosporine agent (e.g., Cequa, Restasis, Vevye)

Documentation Requirements

- Chart notes
- Supporting clinical documentation with evidence of improvement in given indication
- Lab values that confirm safe use from above criteria

Continuation Therapy Criteria Approval Duration

- 12 months OR end of plan year

Criteria for Off-Label Use Requests:

Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. Off-Label Use of Non-Cancer Medications
2. Off-Label Use of Cancer Medications

Description:

Verkazia (cyclosporine) ophthalmic emulsion 0.1% is a calcineurin inhibitor immunosuppressant indicated for the treatment of vernal keratoconjunctivitis (VKC) in children and adults. Following ocular administration, cyclosporine is thought to act by blocking the release of pro-inflammatory cytokines such as IL-2. The exact mechanism of action in the treatment of VKC is not known.

VKC is a severe form of a recurrent, bilateral allergic inflammation of the conjunctiva and the superficial cornea that usually affects prepubertal boys living in warm/hot, dry, tropical and subtropical climates. The peak incidence of VKC is between 7-12 years of age. Like allergic conjunctivitis, it can vary with the seasons, it also is seen as a chronic disorder with episodic acute exacerbations. VKC infrequently occur in adults. Individuals are said to usually "outgrow" the disease with the onset of puberty, although it may persist in adulthood. It presents with intense ocular itching, pain, stringy mucoid discharge, photophobia, tearing, burning, foreign body sensation, and cobblestone-like papillae of the upper eyelid.

Symptoms are most often initially seasonal (spring), and the upper eyelid (tarsus) is predominantly affected. Individuals with VKC often develop giant papillae on the conjunctival lining of the upper eyelid. VKC can cause severe damage to the ocular surface leading to corneal scaring and threaten sight if not properly treated.

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Several classes of pharmacologic agents are available for the treatment of VKC, including lubricating therapies, (e.g., preservative-free artificial tears, gels, or ointments), topical ophthalmic mast-cell stabilizers, ophthalmic antihistamines, dual-acting ophthalmic agents (having both mast-cell stabilizing and antihistaminic activity), and ophthalmic nonsteroidal anti-inflammatory agents. Topical corticosteroids are often necessary in moderate to severe disease. However, these agents are used for short treatment courses due to severe adverse effects such as cataracts, glaucoma, and secondary corneal infections. Topical cyclosporine A (CsA) is effective in controlling ocular surface inflammation in VKC.

Definitions:

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting
MedWatch Forms for FDA Safety Reporting | FDA

Resources:

Verkazia (cyclosporine) ophthalmic emulsion 0.1% product information, revised by Harrow Eye, LLC. 01-2026. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed February 12, 2026.

Hamrah P, Dana R. Vernal keratoconjunctivitis In: UpToDate, Wood RA, Jacobs DS, Li H, TePas E (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through March 2026. Topic last updated July 18, 2025. Accessed April 03, 2026.

Hamrah P, Dana R. Atopic keratoconjunctivitis In: UpToDate, Jacobs DS, Li H (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through March 2026. Topic last updated January 15, 2026. Accessed April 03, 2026.

Hamrah P, Dana R. Allergic conjunctivitis: Clinical manifestations and diagnosis. In: UpToDate, Jacobs DS, Li H (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through March 2026. Topic last updated March 22, 2024. Accessed April 03, 2026.

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Leonardi A, Righetti G, Giovannini G, et al.: Diagnostic criteria of chronic conjunctivitis: atopic keratoconjunctivitis and vernal keratoconjunctivitis. Current Opinion Allergy Clinical Immunology 2023 Oct; 23(5):390-396. *DOI:* 10.1097/ACI.0000000000000915. Accessed March 09, 2025. Re-evaluated April 03, 2026.

ClinicalTrials.gov Bethesda (MD): National Library of Medicine (US). Identifier NCT01751126: Double-Masked Trial of NOVA22007 (1mg/mL Ciclosporin/Cyclosporine) Versus Vehicle in Pediatric Patients With Active Severe Vernal Keratoconjunctivitis. Available from: http://clinicaltrials.gov. Last update posted March 28, 2022. Last verified March 2022. Accessed May 14, 2022. Re-evaluated April 03, 2026.

ClinicalTrials.gov Bethesda (MD): National Library of Medicine (US). Identifier NCT00328653: Efficacy and Tolerance of NOV22007 Versus Vehicle in Patients With Vernal Keratoconjunctivitis. Available from: http://clinicaltrials.gov. Last update posted December 14, 2021. Last verified November 2021. Accessed May 14, 2022. Re-evaluated April 03, 2026.