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 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.

Criteria:

- **Criteria for initial therapy:** Verkazia (cyclosporine) ophthalmic emulsion and/or generic equivalent (if available) is considered ***medically necessary*** and will be approved when **ALL** the following criteria are met:

  1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with an Ophthalmologist or Optometrist

  2. Individual is between 4 years of age and 18 years of age

  3. Individual has a confirmed diagnosis of active, moderate to severe bilateral vernal keratoconjunctivitis (VKC) with severe keratitis and is **ONE** of the following:
     a. Seasonal VKC and provider must submit evidence of seasonality in the spring
     b. Continuous VKC and provider must submit evidence of continuous nature of the disease

4. Individual has a history of at least one recurrence of active, moderate to severe vernal keratoconjunctivitis (VKC) in the past year

5. Individual has at least **TWO** of the following **signs** in at least **one eye**:
    a. Presence of giant papillae with a diameter ≥ 1 mm on the upper tarsal conjunctiva
    b. Superficial keratitis
    c. Conjunctival and episcleral hyperemia
    d. Corneal shield ulcers
    e. Ptosis
    f. Blepharospasm

6. Individual has at least **TWO** of the following **ocular symptoms** in at least **one eye** (the same eye as above): Burning/stinging, tearing, itching, pain, sticky eyelids, foreign body sensation, thick mucus discharge, blurred vision, and photophobia

7. **If available:** Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

8. Individual has documented failure, contraindication per FDA label, intolerance, or is not a candidate for **ONE** of each of the following:
    a. **ONE** of the following dual acting topical mast cell stabilizer/antihistamine agents used with or without an oral non-sedating antihistamine:
        i. Olopatadine (Pataday or generic)
        ii. Ketotifen (Zaditor or generic)
        iii. Azelastine
        iv. Epinastine (Elestat or generic)
    b. **ONE** of the following topical mast cell stabilizers used with or without an oral non-sedating antihistamine:
        i. Cromolyn
        ii. Alocril (nedocromil)
        iii. Alomide (lodoxamide)
    c. Topical cyclosporine 0.05% emulsion (Restasis or generic)

9. Individual **does NOT have any** of the following:
    a. Ocular anomaly other than VKC interfering with the ocular surface including trauma, post radiation keratitis, severe blepharitis, rosacea, corneal ulcer, etc.
    b. Active herpes keratitis or history of ocular herpes or active ocular herpes
    c. Active herpes
    d. Any other active ocular infection (viral, bacterial, fungal, protozoal)
    e. Ocular surgery within prior 6 months
    f. Presence or history of severe systemic allergy

Initial approval duration: 6 months

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- **Criteria for continuation of coverage (renewal request):** Verkazia (cyclosporine) and/or generic equivalent (if available) is considered ***medically necessary*** and will be approved when **ALL** the following criteria are met **(samples are not considered for continuation of therapy)**:

  1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with an Ophthalmologist or Optometrist

  2. Individual's condition has responded while on therapy with response defined as **THREE** of the following:
     a. There has been a reduced need for topical corticosteroid rescue medication over baseline
     b. There has been a reduction in corneal ulcerations over baseline
     c. There has been a reduction in keratitis over baseline
     d. Best corrected distance visual acuity (BCDVA) has improved or has stabilized
     e. There has been marked improvement in itching or mucus discharge or the individual is completely free of all symptoms

  3. Individual has been adherent with the medication

  4. **If available:** Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

  5. For an individual with continuous VKC, provider must submit evidence of continuous nature of the disease

  Renewal duration: 12 months

- 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 more severe form of conjunctivitis that usually affects prepubertal boys living in warm, dry, 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. Patients usually "outgrow" the disease with the onset of puberty. It presents with intense ocular itching, stringy mucoid discharge, and cobblestone-like papillae of the upper eyelid.

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Symptoms are most often initially seasonal (spring), and the upper eyelid (tarsus) is predominantly affected. Patients 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.

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 Santen Incorporated. 06-2022. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed March 18, 2024.

Hamrah P, Dana R. Vernal keratoconjunctivitis In: UpToDate, Wood RA, Jacobs DS, TePas E (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through February 2024. Topic last updated August 07, 2023. Accessed March 18, 2024.

Hamrah P, Dana R. Atopic keratoconjunctivitis In: UpToDate, Jacobs DS, Feldwig AM E (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through February 2024. Topic last updated September 17, 2023. Accessed March 18, 2024.

Hamrah P, Dana R. Allergic conjunctivitis: Clinical manifestations and diagnosis. In: UpToDate, Jacobs DS, Feldwig AM E (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through February 2024. Topic last updated May 23, 2022. Accessed March 18, 2024.

Leonardi A, Doan S, Amrane M, et al.: A Randomized, Controlled Trial of Cyclosporine A Cationic Emulsion in Pediatric Vernal Keratoconjunctivitis. The VEKTIS Study. Ophthalmology 2019 126 May (No 5): 671-681. Accessed May 16, 2022. Re-evaluated March 18, 2024.

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 March 18, 2024.

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 March 18, 2024.