BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 5/19/2022
LAST REVIEW DATE:
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

VERKAZIA® (cyclosporine) ophthalmic emulsion

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. **All requested data must be provided.** Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

VERKAZIA® (cyclosporine) ophthalmic emulsion

Criteria:

- **Criteria for initial therapy:** Verkazia (cyclosporine) ophthalmic emulsion is considered ***medically necessary*** and will be approved when **ALL** of 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 4 to less than 18 years of age

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

7. Documented failure, contraindication per FDA label, intolerance, or not a candidate to **ONE** of each of the following:
    a. **ONE** of the following dual acting topical mast cell stabilizer and antihistamine agents:
        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:
        i. Cromolyn
        ii. Alocril (nedocromil)
        iii. Alomide (lodoxamide)
    c. Topical cyclosporine 0.05% (Restasis or generic)

8. 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.

VERKAZIA® (cyclosporine) ophthalmic emulsion

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

- **Criteria for continuation of coverage (renewal request):** Verkazia (cyclosporine) ophthalmic emulsion is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

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
    a. Response is defined as **THREE** of the following:
        i. There has been a reduced need for topical corticosteroid rescue medication over baseline
        ii. There has been a reduction in corneal ulcerations over baseline
        iii. There has been a reduction in keratitis over baseline
        iv. Best corrected distance visual acuity (BCDVA) has improved or has stabilized
        v. 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. Individual has 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

VERKAZIA® (cyclosporine) ophthalmic emulsion

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.

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.

Resources:

Verkazia (cyclosporine) ophthalmic emulsion product information, revised by Santen Incorporated. 06-2021. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed May 14, 2022.

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. Topic last updated February 07, 2022. Accessed May 15, 2022.

Hamrah P, Dana R. Atopic keratoconjunctivitis In: UpToDate, Jacobs DS, Feldwig AM E (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Topic last updated November 11, 2020. Accessed May 15, 2022.

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. Topic last updated May 15, 2020. Accessed May 15, 2022.

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

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.

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.