Pharmacy Policy Bulletin

Title:	Cyclosporine (Verkazia®)
Policy #:	Rx.01.263

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Intent:

The intent of this policy is to communicate the medical necessity criteria for **Cyclosporine (Verkazia®)** as provided under the member's prescription drug benefit.

Description:

Vernal keratoconjunctivitis (VKC) is an allergic inflammation of conjunctiva that is bilateral and usually seasonally recurrent. There are three types of vernal conjunctivitis: palpebral (papillae primarily involving upper tarsal conjunctiva), limbal (papillae located at limbus), and mixed (components of both palpebral and limbal types). Histopathologic exam of affected conjunctiva shows small lymphoid follicles composed of increased mast cells, eosinophils, and lymphocytes, mononuclear cells and macrophages, CD4 T lymphocytes and B lymphocytes, fibroblasts, and newly secreted collagen (extracellular matrix components). As disease progresses, cellular infiltration and new collagen deposition form giant papillae (squamous epithelial hyperplasia and dense fibrous tissue containing inflammatory cells). Inflammation of limbal palisades and tarsal conjunctiva produces nodules, due to firm attachments of conjunctiva.

Cyclosporine is a calcineurin inhibitor immunosuppressant agent when administered systemically. 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.

Verkazia® ophthalmic emulsion is a calcineurin inhibitor immunosuppressant indicated for the treatment of vernal keratoconjunctivitis in children and adults.

Policy:

INITIAL CRITERIA Cyclosporine (Verkazia®) is approved when ALL of the following are met:

1. Diagnosis of moderate to severe vernal keratoconjunctivitis confirmed by the presence of clinical signs and symptoms (e.g., itching, photophobia, giant papillae at the upper tarsal conjunctiva or at the limbus, thick mucus discharge, conjunctival hyperaemia); and
2. Inadequate response or inability to tolerate one of the following:
    a. Topical ophthalmic “dual-acting” mast cell stabilizer and antihistamine (e.g., olopatadine, azelastine); or
    b. Topical ophthalmic mast cell stabilizers (e.g., cromolyn); and
3. Inadequate response or inability to tolerate short term use (up to 2 to 3 weeks), of topical ophthalmic corticosteroids (e.g., dexamethasone, prednisolone, fluoromethalone); and
4. Prescribed by or in consultation with one of the following:
    a. Ophthalmologist or
    b. Optometrist

Initial authorization duration: 6 months

REAUTHORIZATION CRITERIA Cyclosporine (Verkazia®) is re-approved when there is documentation of positive clinical response to therapy as evidenced by an improvement in clinical signs and symptoms (e.g., itching, photophobia, papillary hypertrophy, mucus discharge, conjunctival hyperaemia).

Reauthorization duration: 2 years

Black Box Warning as shown in the drug Prescribing Information:

N/A

Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

References:

DynaMed. Vernal Keratoconjunctivitis. EBSCO Information Services. Accessed August 8, 2022. https://www.dynamed.com/condition/vernal-keratoconjunctivitis

Verkazia® (cyclosporine) [package insert]. Emeryville, CA: Santen Incorporated; June 2021. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214965s000lbl.pdf. Accessed August 08, 2022.

Applicable Drugs:

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand Name	Generic Name
Verkazia®	Cyclosporine

Cross References:

Rx.01.33 Off Label Use

Rx.01.76 Quantity Level Limits for Pharmaceuticals Covered Under the Prescription Drug Benefit

Policy Version Number:	1.00
P&T Approval Date:	June 09, 2022
Policy Effective Date:	October 01, 2022
Next Required Review Date:	June 09, 2023