| Pharmacy Policy Bulletin: J-1201 Verkazia (cyclosporine ophthalmic emulsion) – Commercial and Healthcare Reform | |
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| **Number:** J-1201 | **Category:** Prior Authorization |
| **Line(s) of Business:**<br>☒ Commercial<br>☒ Healthcare Reform<br>☐ Medicare | **Benefit(s):**<br>**Commercial:**<br>**Prior Authorization (1.):**<br>1. Other Managed Prior Authorization = Yes w/ Prior Authorization<br><br>**Healthcare Reform:** Not Applicable |
| **Region(s):**<br>☒ All<br>☐ Delaware<br>☐ New York<br>☐ Pennsylvania<br>☐ West Virginia | **Additional Restriction(s):**<br>None |
| **Version:** J-1201-004 | **Original Date:** 08/03/2022 |
| **Effective Date: 08/23/2024** | **Review Date:** 08/07/2024 |

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| **Drugs Product(s):** | • Verkazia (cyclosporine ophthalmic emulsion) 0.1% |
| **FDA-Approved Indication(s):** | • Treatment of vernal keratoconjunctivitis (VKC) in children and adults |

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| **Background:** | • Verkazia (cyclosporine ophthalmic emulsion) is an ophthalmic calcineurin inhibitor immunosuppressant agent. Following ocular administration, Verkazia blocks the release of pro-inflammatory cytokines such as interleukin (IL)-2. The exact mechanism of action in the treatment of VKC is unknown.<br>• VKC is a chronic, allergic, and potentially severe ocular disease that can lead to impaired quality of life and loss of vision. An estimated 67 patients are diagnosed with VKC every year in the United States. VKC will often resolve after puberty, and an association with other allergic states such as asthma, eczema, and rhinitis has been observed.<br>• The American Academy of Ophthalmology generally recommends ophthalmic mast cell stabilizers (e.g., cromolyn sodium) and antihistamines (e.g., olopatadine) as first-line therapy. Ophthalmic corticosteroids (e.g., dexamethasone, prednisolone, fluorometholone) are recommended as second-line therapy. Ophthalmic immunomodulating agents (e.g., cyclosporine) are recommended as third-line therapy.<br>• VKC Bonini Severity Scale<br>o 0 (quiescent) = absence of symptoms<br>o 1 (mild) = presence of symptoms with no corneal involvement<br>o 2 (moderate) = presence of symptoms associated with photophobia with no corneal involvement<br>o 3 (severe) = presence of symptoms associated with photophobia and mild to moderate superficial punctate keratopathy<br>o 4 (very severe) = presence of symptoms associated with photophobia and diffuse superficial punctate keratopathy or corneal ulcer |

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| | • Prescribing Considerations:<br>o Verkazia should be prescribed by or in consultation with an ophthalmologist. |

## Approval Criteria

**I. Initial Authorization**

When a benefit, coverage of Verkazia may be approved when all of the following criteria are met **(A., B., and C.)**:

**A.** The member is 4 years of age or older.

**B.** The member has a diagnosis of moderate to severe VKC. (ICD-10: H16.26)

**C.** The member has experienced therapeutic failure or intolerance to two (2) of the following unique medication classes, or all are contraindicated **(1., 2., or 3.)**:

**1.** Generic ophthalmic antihistamines (e.g., olopatadine)

**2.** Generic ophthalmic mast cell stabilizers (e.g., cromolyn sodium)

**3.** Generic ophthalmic corticosteroids (e.g., dexamethasone, prednisolone, fluorometholone)

**II. Reauthorization**

When a benefit, reauthorization of Verkazia may be approved when the following criterion is met **(A.)**:

**A.** The prescriber attests that the member has experienced positive clinical response to therapy.

**III.** An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

## Limitations of Coverage

**I.** Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

**II.** For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

## Authorization Duration

- Commercial and HCR Plans: If approved, up to a 12 month authorization may be granted.

## Automatic Approval Criteria

None

**References:**


1. Verkazia [package insert]. Emeryville, CA: Santen Inc.; June 2021.
2. Leonardi A, Doan S, Amrane M, et al. A Randomized, Controlled Trial of Cyclosporine A Cationic Emulsion in Pediatric Vernal Keratoconjunctivitis. *Ophthalmology* 2019;126(5):671-681.
3. Kraus C. Vernal Keratoconjunctivitis. American Academy of Ophthalmology, Knights Templar Eye Foundation, Pediatric Ophthalmology Education Center. Available at: https://www.aao.org/disease-review/vernal-keratoconjunctivitis-5. Accessed June 24, 2024.
4. Burrow MK, Patel BC. Keratoconjunctivitis. StatPearls. Available at: https://www.ncbi.nlm.nih.gov/books/NBK542279/. Accessed June 24, 2024.
5. Bonini S, Sacchetti M, Mantelli F, et al. Clinical grading of vernal keratoconjunctivitis. *Curr Opin Allergy Clin Immunol.* 2007; 7:436–44.