Clinical Policy: Cyclosporine (Verkazia)

Reference Number: ERX.NPA.159
Effective Date: 12.01.21
Last Review Date: 05.22
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Cyclosporine ophthalmic (Verkazia®) is a topical calcineurin inhibitor immunosuppressant.

FDA Approved Indication(s)
Verkazia is indicated for the treatment of vernal keratoconjunctivitis (VKC) in children and adults.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Verkazia is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Vernal Keratoconjunctivitis (must meet all)**:**

1. Diagnosis of VKC;
2. Age ≥ 4 years;
3. Failure of artificial tears at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
4. Failure of a topical mast cell stabilizer and topical antihistamine (as a single dual-acting product or as two products used in combination; *see Appendix B for examples*) at up to maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated;
5. Verkazia is not prescribed in combination with other ophthalmic cyclosporine products (e.g., Cequa™, Restasis®);
6. Request does not exceed 120 vials per affected eye per 30 days.

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. Verkazia is not prescribed in combination with other ophthalmic cyclosporine products (e.g., Cequa, Restasis);
4. If request is for a dose increase, request does not exceed 120 vials per affected eye per 30 days.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
VKC: vernal keratoconjunctivitis

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
artificial tears (e.g., Visine dry eye relief)	1 to 2 drops in affected eye(s) BID or QID	Various
topical dual-acting mast cell stabilizer/ antihistamine for VKC (e.g., azelastine, bepotastine, epinastine, ketotifen, olopatadine)	1 to 2 drops in affected eye(s) per day	Various
topical mast cell stabilizer for VKC (e.g., cromolyn, lodoxamide, nedocromil)	2 to 6 drops in affected eye(s) per day	Various
topical antihistamine for VKC (e.g., alcaftadine, emedastine)	1 to 4 drops in affected eye(s) per day	Various

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings
None reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
VKC	1 drop QID in each affected eye	4 drops/day in each eye

VI. Product Availability

Single use vial: 0.1% (1 mg/mL), 0.3 mL each of 30, 60, or 120 vials/box

VII. References

1. Verkazia Prescribing Information. Emeryville, CA: Santen Inc; June 2021. Available at: https://www.verkazia.com. Accessed January 13, 2022.
2. American Academy of Ophthalmology Cornea/External Disease Committee. Preferred Practice Pattern® Guidelines. Conjunctivitis. Chicago, IL: American Academy of Ophthalmology; November 2018. Available at: www.aao.org/ppp. Accessed January 13, 2022.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	07.16.21	11.21
2Q 2022 annual review: no significant changes; references reviewed and updated.	01.13.22	05.22

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.