Drug Coverage Policy

Effective Date.....06/01/2024
Coverage Policy Number.....IP0439
Policy Title.....Verkazia

Ophthalmology – Verkazia

- Verkazia® (cyclosporine 0.1% ophthalmic emulsion – Santen)

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment and have discretion in making individual coverage determinations. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Cigna Healthcare Coverage Policy

OVERVIEW

Verkazia, a calcineurin inhibitor immunosuppressant, is indicated for the treatment of **vernal keratoconjunctivitis** (VKC) in patients ≥ 4 years of age.[1]

Disease Overview

VKC, a type of allergic conjunctivitis, is a recurrent, bilateral allergic inflammation of the conjunctiva and the superficial cornea.[3,4] VKC is more common in males and is more prevalent in hot, dry climates and in tropical and sub-tropical countries.[4] Common symptoms include itching, photophobia, burning, foreign body sensation, mucoid discharge, and tearing. It is thought that both immunoglobulin E (IgE)-mediated and cell-mediated immune mechanisms are responsible for exacerbations.

Treatment of VKC depends on the extent and severity of the disease at the time of presentation.[3,4] First-line treatment are lubricating therapies, e.g., preservative-free artificial tears, gels, or ointments. Treatment of moderate cases includes use of ophthalmic mast cell stabilizers (e.g., cromolyn, nedocromil, lodoxamide) and ophthalmic antihistamines. Dual-action ophthalmic products that contain a mast cell stabilizer and an antihistamine are preferred for moderate to severe cases; these agents have a quick onset of action. Ophthalmic nonsteroidal anti-inflammatory agents and ophthalmic corticosteroids have also shown beneficial effects. Intraocular pressure should be monitored in patients receiving ophthalmic corticosteroids. Steroid-sparing agents such as topical immunomodulators (e.g., cyclosporine 0.05% to 2%) are safe alternatives for patients with recurrent episodes.

Guidelines
Verkazia is not addressed in guidelines. The American Academy of Ophthalmology Conjunctivitis Preferred Practice Pattern (PPP) recommendations (2018) note that ophthalmic cyclosporine products have shown to reduce signs and symptoms compared with placebo in patients with VKC.[4] With regards to vernal/atopic conjunctivitis, the PPP notes ophthalmic mast cell stabilizers and ophthalmic antihistamines are efficacious. In addition, ophthalmic corticosteroids are usually necessary to control signs and symptoms of acute exacerbations of vernal/atopic conjunctivitis.

Medical Necessity Criteria

Verkazia is considered medically necessary when the following criteria are met:

FDA-Approved Indication

1. **Vernal Keratoconjunctivitis.** Approve for 1 year if the patient meets the following (A, B, C, D, and E):
   - **A)** Patient is ≥ 4 years of age; AND
   - **B)** According to the prescriber, the patient has moderate to severe vernal keratoconjunctivitis; AND
   - **C)** Patient meets one of the following (i or ii):
     - **i.** Patient has tried two single-action ophthalmic medications (i.e., ophthalmic mast cell stabilizers or ophthalmic antihistamines) for the maintenance treatment of vernal keratoconjunctivitis; OR
       Note: Examples of single-action ophthalmic medications for the maintenance treatment of vernal keratoconjunctivitis include ophthalmic mast cell stabilizers (e.g., cromolyn ophthalmic solution, Alomide (lodoxamide ophthalmic solution]) and ophthalmic antihistamines (e.g., Zerviate [cetirizine ophthalmic solution]).
     - **ii.** Patient has tried one dual-action ophthalmic mast-cell stabilizer/antihistamine product for the maintenance treatment of vernal keratoconjunctivitis; AND
       Note: Examples of dual-action ophthalmic mast cell stabilizer/antihistamine products include azelastine ophthalmic solution, bepotastine ophthalmic solution, epinastine ophthalmic solution, Lastacaft, and olopatadine ophthalmic solution.

   Note: An exception to the requirement for a trial of two single-action ophthalmic medications (i.e., ophthalmic mast cell stabilizers or ophthalmic antihistamines) or one dual-action ophthalmic mast cell stabilizer/antihistamine product for the maintenance treatment of vernal keratoconjunctivitis can be made if the patient has already tried at least one ophthalmic cyclosporine product (e.g., Cequa [cyclosporine 0.09% ophthalmic solution], Restasis [cyclosporine 0.05% ophthalmic emulsion], Vevye [cyclosporine 0.1% ophthalmic solution]) other than the requested medication.

D) The medication is prescribed by or in consultation with an optometrist or ophthalmologist; AND

E) Preferred product criteria is met for the products listed in the below table(s)

Employer Plans:

Product	Criteria
Verkazia (cyclosporine 0.1% ophthalmic emulsion)	**<u>Standard/Performance/Legacy Drug List Plans:</u>** **ONE** of the following: 1. Failure or intolerance to an ophthalmic cyclosporine medication (for example, Cequa, Restasis) 2. Failure, contraindication, or intolerance to **EITHER** of the following: A. **TWO** single-action ophthalmic medications (for example, Cromolyn, Alomide, Zerviate) B. **ONE** dual-action ophthalmic mast-cell stabilizer/antihistamine medication (for example, azelastine, bepotastine, epinastine, olopatadine) **<u>Value/Advantage/Total Savings Drug List Plans:</u>** **ONE** of the following: 1. Failure or intolerance to an ophthalmic cyclosporine medication (for example, Cequa, Restasis) 2. Failure, contraindication, or intolerance to **EITHER** of the following: A. **ONE** single-action ophthalmic medication (for example, Cromolyn) B. **ONE** dual-action ophthalmic mast-cell stabilizer/antihistamine medication (for example, azelastine, bepotastine, epinastine, olopatadine) [dual-action ophthalmic mast-cell stabilizer/antihistamine medications are specifically excluded under some Value, Advantage and Cigna Total Savings Prescription Drug List Plans. Please refer to the applicable benefit plan document to determine benefit availability]

Individual and Family Plans:

Product	Criteria
Verkazia (cyclosporine 0.1% ophthalmic emulsion)	**ONE** of the following: 1. Failure or intolerance to an ophthalmic cyclosporine medication (for example, Restasis, Cequa [may require prior authorization]) 2. Failure, contraindication, or intolerance to **EITHER** of the following: A. **TWO** single-action ophthalmic medications (for example, Cromolyn, Alomide, Zerviate [may require prior authorization])

Product	Criteria
	B. **ONE** dual-action ophthalmic mast-cell stabilizer/antihistamine medication (for example, azelastine, epinastine, olopatadine)

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven (criteria will be updated as new published data are available).

References

1. Verkazia® ophthalmic emulsion [prescribing information]. Emeryville, CA: Santen; June 2021.
2. Varu D, Rhee M, Akpek E, et al. American Academy of Ophthalmology Preferred Practice Pattern Cornea and External Disease Panel. Conjunctivitis Preferred Practice Pattern®. *Ophthalmology*. 2019;126:P94-P169.
3. Burrow MK, Patel BC. Keratoconjunctivitis. [Updated 2023 Aug 7]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK542279/. Accessed on January 23, 2024.
4. Kaur K, Gurnani B. Vernal Keratoconjunctivitis. [Updated 2023 Jun 11]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK576433/. Accessed on January 23, 2024.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	No criteria changes	06/01/2024

The policy effective date is in force until updated or retired.