Effective Date 8/1/2023
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Coverage Policy Number IP0439

Verkazia

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Related Coverage Resources

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. 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.

Overview

This policy supports medical necessity review for cyclosporine 0.1% ophthalmic emulsion (**Verkazia**®).

Additional criteria that support the review for medical necessity exceptions of non-covered products are located in the Non-Covered Product Table by the respective plan type and drug list where applicable.

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

Medical Necessity Criteria

Cyclosporine 0.1% ophthalmic emulsion (**Verkazia**) **is considered medically necessary when the following are met:**

1. **Vernal Keratoconjunctivitis.** Individual meets **ALL** of the following criteria:
   A. Age 4 years or older
   B. According to the prescriber, the individual has moderate to severe vernal keratoconjunctivitis

C. Medication is prescribed by, or in consultation with, an optometrist or ophthalmologist
D. Non-Covered Product Criteria is met, refer to below table(s)

Employer Group Non-Covered Products and Criteria:

Non-Covered Product	Criteria
Verkazia (cyclosporine 0.1% ophthalmic emulsion)	**<u>Standard/Performance/Legacy Drug List Plans:</u>** Documentation of **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/Cigna Total Savings Drug List Plans:</u>** Documentation of **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 Plan Non-Covered Products and Criteria:

Non-Covered Product	Criteria
Verkazia (cyclosporine 0.1% ophthalmic emulsion)	Documentation of **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]) 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.

Reauthorization Criteria

Continuation of cyclosporine 0.1% ophthalmic emulsion (Verkazia) is considered medically necessary for vernal keratoconjunctivitis when the above medical necessity criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial and reauthorization approval duration: up to 12 months

Conditions Not Covered

Any other use is considered experimental, investigational or unproven.

Background

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

Guidelines
Verkazia is not addressed in guidelines. However, ophthalmic cyclosporine products (in strengths of 0.05% and 2%) are discussed for the treatment of vernal keratoconjunctivitis in the American Academy of Ophthalmology Conjunctivitis Preferred Practice Pattern recommendations (2018).[2] Commercially available 0.05% ophthalmic cyclosporine has demonstrated efficacy with more frequent dosing for the treatment of vernal conjunctivitis. It has been shown to reduce signs and symptoms, prevent seasonal recurrences, and may reduce use of topical steroids. Besides cyclosporine, other medications recommended for maintenance of vernal keratoconjunctivitis include ocular lubricants, antihistamines (oral and ophthalmic), and ophthalmic mast-cell stabilizers. Ophthalmic corticosteroids are reserved for acute exacerbations.

References

1. Verkazia® ophthalmic emulsion [prescribing information]. Emeryville, CA: Santen; June 2022.
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.