Drug and Biologic Coverage Policy

**Effective Date** ..... **1/1/2023**
**Next Review Date…** ..... **1/1/2024**
**Coverage Policy Number** ..... **IP0474**

# Tobramycin/loteprednol etabonate (Zylet) Ophthalmic Suspension for Individual and Family Plans

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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 tobramycin 0.3%/loteprednol etabonate 0.5% ophthalmic suspension (Zylet®) for Individual and Family Plans.

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

## Medical Necessity Criteria

**Coverage varies across plans and requires the use of preferred products. Refer to the customer's benefit plan document for coverage details.**

**The product in the table below is considered medically necessary when the following are met:**

**Individual and Family Plan Non-Covered Products and Covered Alternative(s):**

| Non-Covered Product | Criteria |
|---|---|
| **Zylet**<br><br>(tobramycin 0.3%/loteprednol etabonate 0.5% ophthalmic suspension) | Individual meets **ONE** of the following (1, 2, or 3):<br>1. The individual has had an inadequate response, contraindication, or is intolerant to the following:<br>A. tobramycin/dexamethasone ophthalmic suspension<br>2. Individual is less than 2 years of age<br>3. Individual is currently receiving Zylet for the treatment of active eye infections |

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

Not applicable for continuation beyond initial approval duration.

## Authorization Duration

Initial approval duration: up to 6 weeks
Reauthorization approval duration: Not applicable.

## Conditions Not Covered

Any other use is considered experimental, investigational or unproven.

## Background

**OVERVIEW**
Zylet is a combination of loteprednol etabonate, a corticosteroid, and tobramycin, an aminoglycoside antibacterial, indicated for steroid-responsive inflammatory ocular conditions for which a corticosteroid is indicated and where superficial bacterial ocular infection or a risk of bacterial ocular infection exists.[1]

## References

1. Zylet® ophthalmic suspension [prescribing information]. Bridgewater, NJ: Bausch + Lomb; October 2021.