



Drug Coverage Policy

Effective Date5/15/2025

Coverage Policy Number.....IP0371

Policy Title..... Xipere

Ophthalmology – Xipere

- Xipere® (triamcinolone acetonide suprachoroidal injection – Bausch & Lomb)

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 where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see “Coding Information” below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. 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

*Xipere, a corticosteroid, is indicated for the treatment of **macular edema associated with uveitis**.¹*

The recommended dose of Xipere is 4 mg (0.1 mL of the 40 mg/mL injectable suspension); Xipere is given as a suprachoroidal injection (injection between the choroid and sclera).^{1,2} In the pivotal study, Xipere was given on Day 0 and Week 12.^{1,3} Safety and effectiveness of Xipere in pediatric patients have not been established.

Disease Overview

Uveitis, inflammation of the uveal tract (the vascular layer between the sclera and the neuroretina), can lead to significant visual impairment.^{2,4,5} Depending on the primary location of the inflammation, uveitis can be classified into anterior, intermediate, posterior, or panuveitis. In non-infectious uveitis, macular edema is the most common complication (approximately 8% of patients with non-infectious uveitis). Macular edema associated with uveitis, if left untreated, may result in damage to photoreceptors and permanent vision loss. Treatment options for macular edema associated with non-infectious uveitis include ophthalmic corticosteroids (e.g., Ozurdex[®] [dexamethasone intravitreal implant], Yutiq[®] [fluocinolone acetonide intravitreal implant], Retisert[®] [fluocinolone acetonide intravitreal implant], Triesence[®] [triamcinolone acetonide intravitreal injection], and Xipere[®] [suprachoroidal triamcinolone acetonide injection]) and ophthalmic non-steroidal anti-inflammatory (NSAIDs).⁴

Coverage Policy

POLICY STATEMENT

Prior Authorization is required for prescription benefit coverage of Xipere. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Xipere as well as the monitoring required for adverse events and long-term efficacy, approval requires Xipere to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Xipere is considered medically necessary when the following criteria is met:

FDA-Approved Indication

- 1. Macular Edema Associated with Uveitis. Approve for 6 months if the patient** meets **ALL** of the following (A, B, C, and D):
 - A)** Patient is ≥ 18 years of age; **AND**
 - B)** Patient has non-infectious uveitis (i.e., pan, anterior, intermediate, or posterior); **AND**
 - C)** The medication is prescribed by, or in consultation with, an ophthalmologist; **AND**
 - D)** Preferred product criteria is met for the product as listed in the below tables

Employer Plans:

Product	Criteria
Xipere[®] (triamcinolone acetonide 40 mg/mL suprachoroidal injection)	ONE of the following: <ol style="list-style-type: none"> 1. Patient has tried Triesence ophthalmic injectable suspension 2. Patient has already started on Xipere and requires Xipere to complete the course of treatment.

Individual and Family Plans:

Product	Criteria
Xipere[®] (triamcinolone acetonide 40 mg/mL)	ONE of the following: <ol style="list-style-type: none"> 1. Patient has tried Triesence ophthalmic injectable suspension

Product	Criteria
suprachoroidal injection)	2. Patient has already started on Xipere and requires Xipere to complete the course of treatment.

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.

Xipere for any other use is considered not medically necessary, including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

- 1. Concomitant Use with Another Intravitreal Corticosteroid.** There is no evidence to support concomitant use of Xipere with another intravitreally administered corticosteroid.
Note: Examples of intravitreally administered corticosteroid are Ozurdex[®] [dexamethasone intravitreal implant], Yutiq[®] [fluocinolone acetonide intravitreal implant], Retisert[®] [fluocinolone acetonide intravitreal implant], and Triescence[®] [triamcinolone acetonide intravitreal injection].

Coding Information

- Note: 1) This list of codes may not be all-inclusive.
 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
J3299	Injection, triamcinolone acetonide (Xipere), 1 mg

References

- Xipere suprachoroidal injection. Bridgewater, NJ: Bausch & Lomb; September 2022.
- Teper SJ. Update on the management of uveitic macular edema. *J. Clin. Med.* 2021.10(18), 4133; <https://doi.org/10.3390/jcm10184133>.
- Yeh S, Khurana RN, Shah M, et al. Efficacy and safety of suprachoroidal CLS-TA for macular edema secondary to noninfectious uveitis: phase 3 randomized trial. *Ophthalmology.* 2020;127:948-955.
- Massa H, Pipis SY, Adewoyin T, et al. Macular edema associated with non-infectious uveitis: pathophysiology, etiology, prevalence, impact and management challenges. *Clin Ophthal.* 2019;13:1761-1777.
- Emami-Naeini P. Treating uveitic macular edema. Available on: <https://www.retina-specialist.com/article/treating-uveitic-macular-edema>. Reviewed on May 7, 2022. Accessed on July 29, 2024.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	<p>Policy Title: Updated from "Triamcinolone Acetonide Ophthalmic" to "Ophthalmology – Xipere."</p> <p>Macular Edema Associated with Uveitis. Added criteria "Patient is ≥ 18 years of age." Removed criteria "Individual has macular edema associated with non-infectious uveitis."</p> <p>Preferred Product Table: Employer Plans and Individual and Family Plans Updated from "ONLY the following: Triesence (triamcinolone acetonide)" to "ONE of the following: 1. Patient has tried Triesence ophthalmic injectable suspension; 2. Patient has already started on Xipere and requires Xipere to complete the course of treatment." Removed the statement "When coverage requires the use of preferred products, there is documentation of ONE of the following (A or B): A. The individual has had inadequate efficacy to the number of covered alternatives according to the table below; OR B. The individual has a contraindication according to FDA label, significant intolerance, or is not a candidate* for the covered alternatives according to the table below. *Note: Not a candidate due to being subject to a warning per the prescribing information (labeling), having a disease characteristic, individual clinical factor[s], other attributes/conditions, or is unable to administer and requires this dosage formulation." Added criteria "Concomitant Use with Another Intravitreal Corticosteroid" under use considered not medically necessary.</p>	5/15/2025

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

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