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5.22.003

Section:	Prescription Drugs	**Effective Date:**	April 1, 2025
Subsection:	Corticosteroids	**Original Policy Date:**	January 28, 2022
Subject:	Xipere	**Page:**	1 of 4

Last Review Date: March 7, 2025

Xipere

Description

Xipere (triamcinolone acetonide injectable suspension)

Background
Macular edema is fluid build-up in the portion of the eye known as the macula. Fluid can cross into the macula due to a disruption in the uveal tract. Inflammation at any portion of the uveal tract is known as uveitis and can lead to the disruption of the barrier the uveal tract provides and allow fluid and swelling to occur in the macula. Xipere is a corticosteroid injection system designed to treat macular edema associated with uveitis via suprachoroidal administration. The utilization of the suprachoroidal space provides targeted and compartmentalized delivery and higher proportions of absorption relative to intravitreal injection (1-2).

Regulatory Status
FDA-approved indication: Xipere is a corticosteroid indicated for the treatment of macular edema associated with uveitis (2).

Xipere is contraindicated in cases of active or suspected ocular or periocular infections. This includes most viral disease of the cornea and conjunctiva, including active epithelial herpes simplex keratitis, vaccinia, varicella, mycobacterial infections, and fungal diseases (2).

Patients should also be monitored for corticosteroid related effects, such as cataracts, increased intraocular pressure and glaucoma (2).

The safety and effectiveness of Xipere in pediatric patients less than 18 years of age have not been established (2).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Xipere may be considered **medically necessary** if the conditions indicated below are met.

Xipere may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

Macular edema associated with uveitis

AND ALL of the following:

1. **NO** ocular or periocular infection
2. Prescriber will not exceed the FDA labeled dose of 4 mg as a suprachoroidal injection per affected eye

Prior–Approval *Renewal* Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

Macular edema associated with uveitis

AND ALL of the following:

1. **NO** ocular or periocular infection
2. Prescriber will not exceed the FDA labeled dose of 4 mg as a suprachoroidal injection per affected eye
3. Patient has had positive clinical response to treatment (e.g., improvement or maintenance in best corrected visual acuity [BCVA] or visual field, reduction or maintenance in central subfield thickness [CST], a reduction in the rate of vision decline or the risk of more severe vision loss, reduction in inflammation)

Policy Guidelines

Pre–PA Allowance

None

Prior–Approval Limits

Duration 12 months

Prior–Approval *Renewal* Limits

Same as above

Rationale

Summary

Xipere (triamcinolone injectable suspension) is designed to treat macular edema associated with uveitis via suprachoroidal administration. Xipere is contraindicated in the case of ocular or periocular infections. Patients should be monitored for corticosteroid related side effects after injection with Xipere. The safety and effectiveness of Xipere in pediatric patients less than 18 years of age have not been established (2).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Xipere while maintaining optimal therapeutic outcomes.

References

1. U.S. Department of Health and Human Services. (n.d.). *Macular edema*. National Eye Institute. Retrieved January 14, 2022, from https://www.nei.nih.gov/learn-about-eye-health/eye-conditions-and-diseases/macular-edema
2. Xipere [package insert]. Bridgewater, NJ: Bausch & Lomb Americas Inc.; September 2022.

Policy History

Date	Action
January 2022	Addition to PA
March 2022	Annual review
December 2023	Annual review. Changed policy number to 5.22.003
March 2024	Annual review and reference update
December 2024	Annual review and reference update
March 2025	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 7, 2025 and is effective on April 1, 2025.