Subject:	Xipere (triamcinolone acetonide injectable suspension)		
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Overview

This document addresses the use of Xipere (triamcinolone acetonide injectable suspension) for suprachoroidal use. Xipere is the first FDA-approved agent administered via suprachoroidal injection. It is approved for the treatment macular edema associated with uveitis.

Uveitis is a broad term referring to a number of conditions that produce inflammation of the uvea, the vascular layer of the eye sandwiched between the sclera and the retina. Uveitis may affect any part of the uvea, including the anterior (iritis), intermediate (pars planitis), posterior (choroiditis), or the entire uvea (pan-uveitis). Uveitis may affect one or both eyes. Potential causes of uveitis are autoimmune disorders including sarcoidosis, infection, or exposure to toxins. However, the cause remains unknown in most individuals. Topical corticosteroids are often used for anterior uveitis, but are often ineffective for posterior uveitis. Periocular or intraocular glucocorticoid injections are a treatment option, but include the risk of increased ocular pressure, glaucoma, and cataracts.

Xipere (triamcinolone acetonide injectable suspension) for suprachoroidal use was studied in one randomized, sham-controlled trail of individuals with macular edema associated with noninfectious anterior-, intermediate-, posterior-, or pan-uveitis of any cause. Patients were treated at baseline and at week 12 and were allowed rescue therapy including intravitreal or periocular steroids. Xipere was superior to sham injection in percentage of patients with an improvement in vision (≥3 lines of vision) from baseline at week 24 (47% vs 16%, respectively; P<0.001). Treatment-related adverse events occurred in 30% vs 12.5%, respectively, in the Xipere and sham arms, with cataract (7% vs 6%), eye pain (6% vs 0), and vitreous detachment (5.2% vs 1.6%) occurring more frequently in the Xipere arm. The FDA label does not address re-treatment with Xipere, but current published data evaluated the use of two injections separated by 12 weeks (Yeh 2021).

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Xipere (triamcinolone acetonide injectable suspension)

Requests for Xipere (triamcinolone acetonide injectable suspension) for suprachoroidal use may be approved if the following criteria are met:

I. Individual has a diagnosis of noninfectious uveitis; **AND**
II. Individual has evidence of macular edema secondary to uveitis

Requests for Xipere (triamcinolone acetonide injectable suspension) for suprachoroidal use may not be approved for the following:

I. Individual has active or suspected ocular or periocular infections including most viral diseases of cornea and conjunctiva including active epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella, mycobacterial infections, and fungal disease; **OR**
II. When the above criteria are not met and for all other indications.

Approval duration: 1 month

Quantity Limits

Xipere (triamcinolone acetonide injectable suspension) Quantity Limits

Drug	Limit
Xipere (triamcinolone acetonide injectable suspension) 40 mg/mL vial for suprachoroidal use	4 mg (1 single-dose vial) per eye per treatment; repeat treatments may be approved no sooner than 12 weeks after the prior dose.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

J3490	Unclassified drugs [Xipere] (triamcinolone acetonide injectable suspension)
C9092	Injection, triamcinolone acetonide, suprachoroidal (Xipere), 1 mg

ICD-10 Diagnosis

	All diagnoses pend

Document History

Reviewed: 6/13/2022
Document History:

- 06/13/2022 – Annual Review: Create new clinical criteria document for Xipere. Coding Reviewed: J3490, C9092. All diagnoses pend.

References

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3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
5. 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 Jul;127(7):948-955.