Medical Policy

Healthcare Services Department

Policy Name	Policy Number	Scope
Triamcinolone acetonide injectable suspension [Xipere®, Triesence®]	MP-RX-FP-93-23	☒ MMM MA ☒ MMM Multihealth

Service Category

☐ Anesthesia
☐ Surgery
☐ Radiology Procedures
☐ Pathology and Laboratory Procedures
☐ Medicine Services and Procedures
☐ Evaluation and Management Services
☐ DME/Prosthetics or Supplies
☒ Part B DRUG

Service Description

This document addresses the use of *triamcinolone acetonide injectable suspension [Xipere®, Triesence®]* , a corticosteroid approved by the Food and Drug Administration (FDA) for the treatment of ophthalmic diseases.

Background Information

This document addresses the use of triamcinolone acetonide injectable suspension (Xipere, Triesence). Xipere is the first FDA-approved agent administered via suprachoroidal injection. It is approved for the treatment macular edema associated with uveitis. Triesence is a synthetic corticosteroid approved by the U.S. Food and Drug Administration (FDA) for the treatment of specific ophthalmic diseases and for visualization during vitrectomy procedures.

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).

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Triesence is indicated for the treatment of sympathetic ophthalmia, temporal arteritis, uveitis, and ocular inflammatory conditions unresponsive to topical corticosteroids. It is also utilized to enhance visualization during vitrectomy, a surgical procedure that removes the vitreous gel from the eye. The recommended dose for treating ophthalmic diseases is 4 mg (100 microliters of 40 mg/mL suspension), with subsequent doses administered as needed. For visualization during vitrectomy, the recommended dose ranges from 1 to 4 mg (25 to 100 microliters) administered intravitreally. Strict aseptic technique is mandatory during administration to minimize the risk of infection. Potential adverse effects include elevated intraocular pressure, cataracts, and endophthalmitis. Patients should be monitored appropriately following injection to manage these risks.

Approved Indications

Xipere®

A. Treatment of macular edema associated with uveitis.

Triesence®

A. Treatment of the following ophthalmic diseases: sympathetic ophthalmia, temporal arteritis, uveitis, and ocular inflammatory conditions unresponsive to topical corticosteroids.

B. Visualization during vitrectomy.

Other Uses

i. N/A

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Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS	Description
J3299	Injection, triamcinolone acetonide (Xipere), 1 mg
J3300	Injection, triamcinolone acetonide, preservative-free, 1 mg.

ICD-10	Description
H20.9	Uveitis, unspecified
H20.011-H20.019	Primary acute uveitis, anterior
H20.021-H20.029	Recurrent acute uveitis, anterior
H20.11-H20.10	Chronic uveitis, anterior
H43.89	Intermediate uveitis; Vitritis
H30.21-H30.20	Posterior cyclitis
H44.011-H44.013	Panophthalmitis; Endophthalmitis, Acute
H44.021- H44.023	Endophthalmitis, Chronic
H44.111- H44.119	Panuveitis
H44.1	Other endophthalmitis (ocular inflammatory conditions unresponsive to topical corticosteroids)
H44.2	Sympathetic uveitis
H35.021- H35.029	Exudative retinopathy
H35.061- H35.069	Retinal vasculitis
H30.001- H30.009	Unspecified focal chorioretinal inflammation (choroiditis/chorioretinitis - NOS)
H30.011- H30.019	Focal chorioretinal inflammation, juxtapapillary
H30.021- H30.029	Focal chorioretinal inflammation of posterior pole [aka Posterior Uveitis, Posterior Pole
H30.031- H30.039	Focal chorioretinal inflammation, peripheral [aka Posterior Uveitis, Peripheral]
H30.041- H30.049	Focal chorioretinal inflammation, macular or paramacular
H30.101- H30.109	Unspecified disseminated chorioretinal inflammation (chorioretinitis/choroiditis)
H30.111- H30.119	Disseminated chorioretinal inflammation (choroiditis/chorioretinitis) posterior pole
H30.121- H30.129	Disseminated chorioretinal inflammation (chorioretinitis/choroiditis) peripheral
H30.131- H30.139	Disseminated chorioretinal inflammation, generalized
H30.90- H30.93	Unspecified chorioretinal inflammation [aka Retinitis NOS]

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H30.891- H30.899	Other chorioretinal inflammations
H30.811- H30.819	Harada's disease
H20.821- H20.829	Vogt-Koyanagi syndrome
H20.041- H20.049	Secondary noninfectious anterior iridocyclitis [aka HLA-B27 (secondary noninfectious)
M31.6	Other giant cell arteritis (including temporal arteritis)
Z98.89	Postprocedural states (for visualization during vitrectomy)

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Medical Necessity Guidelines

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.

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

triamcinolone acetonide injectable suspension (Xipere®)

A. Criteria for Initial Approval

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.

B. Criteria for Continuation of Therapy

Continuation requests for Xipere (triamcinolone acetonide injectable suspension) may be approved if the following criteria are met:

i. Progress notes or clinical documentation from the prescriber confirms that the patient requires continued treatment and has demonstrated stabilization and/or improvement in disease activity; **AND**
ii. There is no evidence of treatment-limiting adverse effects associated with Xipere.

C. Conditions not Covered

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.

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D. Approval Duration

i. Approval duration: 1 month

triamcinolone acetonide injectable suspension (Triesence®)

A. Criteria for Initial Approval

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

i. Individual has a diagnosis of one of the following diseases:
   A. Sympathetic ophthalmia
   B. Temporal arteritis
   C. Non-infectious uveitis (including anterior, intermediate, posterior, or panuveitis
   D. Ocular inflammatory conditions unresponsive to topical corticosteroids;

OR

ii. Individual need Triesence for perioperative use during vitrectomy for visualization purposes.

B. Criteria for Continuation of Therapy

Continuation of therapy with Triesence (triamcinolone acetonide injectable suspension) typically does not apply as it is primarily used as a single or as needed treatment.

C. Conditions not Covered

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

i. Individual has active or suspected systemic fungal infection;

OR

ii. When the above criteria are not met and for all other indications.

D. Approval Duration

i. Approval duration: 1 month

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Limits or Restrictions

A. Therapeutic Alternatives

The list below includes preferred alternative therapies recommended in the approval criteria and may be subject to prior authorization.

i. N/A

B. Quantity Limitations

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.

Drug	Recommended Dosage
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.
Triesence (triamcinolone acetonide suspension) 40mg/ml vial for intravitreal use	• Treatment of ophthalmic diseases – 4 mg per eye. Subsequent dosage as needed over the course of treatment. • Visualization during vitrectomy – 1 to 4 mg administered intravitreally.

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Reference Information

1. Novartis Pharmaceuticals Corporation. (2023). Triesence® (triamcinolone acetonide injectable suspension) prescribing information. Retrieved from https://www.novartis.com/us-en/sites/novartis_us/files/triesence.pdf
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. URL: http://www.clinicalpharmacology.com. Updated periodically.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: June 9, 2023.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
6. 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.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

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Revision Type	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Choose an item.		Click or tap to enter a date.	Click or tap to enter a date.
Annual Review 9/27/2024	Update background information to include Triesence and clarify suprachoroidal injection applies only to Xipere. Add approved indications per drug, other uses, clinical criteria for Triesence and criteria for continuation therapy for Xipere, quantity limits (dosage table). Update references. Wording and formatting changes. Coding Reviewed: Add ICD10 codes H20.9, H44.2, M31.6, H44.1, Z98.89.	3/14/2025	4/2/2025
Policy Inception 9/27/2023	Elevance Health's Medical Policy adoption.	10/30/2023	11/30/2023