Medical Policy

Utilization Management and Clinical Medical Policy

Policy Name:	Policy Number:	Scope:	Origination Date:	Effective Date:
Triamcinolone acetonide injectable suspension [Xipere®, Triesence®]	**MP-RX-FP-93-23**	☒ **MMM MA** ☒ **MMM MultiHealth**	**11/30/2023** **Last Review Date:** **10/21/2026**	**10/21/2026** **Frequently Revision:** **Annual**

Service Category:

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

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 select ophthalmic diseases and/or visualization during vitrectomy.

Background Information:

This document addresses the use of triamcinolone acetonide injectable suspension (Xipere, Triesence). Xipere is administered via suprachoroidal injection using the SCS Microinjector® and 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 located 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 (panuveitis). Uveitis may affect one or both eyes. Potential causes of uveitis include autoimmune disorders, such as sarcoidosis, infection, or exposure to toxins. However, the cause remains unknown in most individuals. Topical corticosteroids are often used for anterior uveitis but may be inadequate for intermediate, posterior, or panuveitis, particularly when macular edema is present. Periocular or intraocular glucocorticoid injections are a treatment option, but are associated with risks such as increased intraocular pressure, glaucoma, cataracts, and infection. Current ophthalmology literature supports periocular and intraocular corticosteroid therapies as effective options for noninfectious uveitic macular edema, with monitoring for steroid-related ocular adverse effects.

Xipere (triamcinolone acetonide injectable suspension) for suprachoroidal use was studied in one randomized, sham-controlled trial of individuals with anterior, intermediate, posterior, or panuveitis. 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 (≥ 15 letters in best corrected visual acuity [BCVA]) from baseline at week 24 (47% vs 16%, respectively; P<0.001). The most common adverse reactions reported in controlled studies included elevated intraocular pressure, eye pain, cataract, vitreous detachment, injection site pain, conjunctival hemorrhage, reduced visual acuity, dry eye, photophobia, vitreous floaters, and headache. 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 2020).

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)

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administered intravitreally. Strict aseptic technique is mandatory during administration to minimize the risk of infection. Potential adverse effects include elevated intraocular pressure, cataracts, glaucoma, infection, 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

A. None.

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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.

triamcinolone acetonide injectable suspension (Xipere®)

A. Criteria For Initial Approval (*Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met **all** approval criteria.)*

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 uveitis; **AND**
ii. Individual has evidence of macular edema secondary to uveitis confirmed by ophthalmologic examination and/or imaging, such as optical coherence tomography (OCT).

B. Criteria For Continuation of Therapy

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

i. Individual continues to have persistent or recurrent macular edema associated with uveitis requiring additional treatment; **AND**
ii. 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 or visual/anatomic response, including but not limited to improvement or stabilization in best corrected visual acuity (BCVA), central retinal thickness, macular edema, or ocular inflammation; **AND**
iii. There is no evidence of treatment-limiting adverse effects associated with Xipere, including uncontrolled increased intraocular pressure, glaucoma, cataract progression, ocular infection, retinal detachment, or endophthalmitis.

C. Authorization Duration

i. Approval Duration: 1 month

D. Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

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

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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.

triamcinolone acetonide injectable suspension (Triesence®)

A. Criteria For Initial Approval (*Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met **all** approval criteria.)*

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

i. Individual has a diagnosis of one of the following diseases:

A. Sympathetic ophthalmia; **OR**
B. Temporal arteritis; **OR**
C. Uveitis, including anterior, intermediate, posterior, or panuveitis; **OR**
D. Ocular inflammatory conditions unresponsive to topical corticosteroids;

OR

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

B. Criteria For Continuation of Therapy

i. Continuation of therapy with Triesence (triamcinolone acetonide injectable suspension) may be approved for ophthalmic inflammatory disease if documentation confirms that the individual requires subsequent treatment and has demonstrated clinical benefit, disease stabilization, or recurrence/persistence of inflammation requiring additional therapy; **AND**

A. There is no evidence of treatment-limiting adverse effects associated with Triesence, including uncontrolled increased intraocular pressure, glaucoma, cataract progression, ocular infection, retinal detachment, or endophthalmitis.

ii. Continuation of therapy is not applicable when Triesence is used for visualization during vitrectomy.

C. Authorization Duration

i. Approval Duration: 1 month

D. Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

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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. Individual has active ocular herpes simplex;

OR

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

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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) administered as a suprachoroidal injection using the SCS Microinjector®; each single-dose package is for treatment of one eye only. 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 – Initial recommended dose: 4 mg (100 microliters of 40 mg/mL suspension) per eye; subsequent dosage as needed over the course of treatment. • Visualization during vitrectomy – 1 to 4 mg (25 to 100 microliters of 40 mg/mL suspension) administered intravitreally.

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Codes Information:

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.

ICD-10 Diagnostic Codes:

ICD-10	Description
H20.9	Uveitis, unspecified
H20.011-H20.019	Primary acute uveitis [anterior uveitis]
H20.021-H20.029	Recurrent acute uveitis [anterior uveitis]
H20.10-H20.13	Chronic iridocyclitis [anterior uveitis]
H20.20-H20.23	Lens-induced iridocyclitis [anterior uveitis]
H20.811- H20.819	Fuchs' heterochromic cyclitis
H43.89	Other disorders of vitreous body [vitritis]
H44.111- H44.119	Panuveitis
H44.1	Other endophthalmitis (ocular inflammatory conditions unresponsive to topical corticosteroids)
H44.131-H44.139	Sympathetic uveitis
H35.81	Retinal edema
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
H30.20-H30.23	Posterior cyclitis [pars planitis; intermediate uveitis]
H30.90- H30.93	Unspecified chorioretinal inflammation [Retinitis NOS; posterior uveitis]
H30.891- H30.899	Other chorioretinal inflammations [posterior uveitis]
H30.811- H30.819	Harada's disease [posterior uveitis]
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)

HCPCS Codes:

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

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Reference Information:

1. Bausch + Lomb Incorporated. Xipere® (triamcinolone acetonide injectable suspension), for suprachoroidal use: Prescribing Information. Revised May 2025. Accessed July 9, 2026. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/211950s002lbl.pdf
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. URL: http://www.clinicalpharmacology.com. Updated periodically.
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4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Harrow Eye, LLC. Triesence® (triamcinolone acetonide injectable suspension) 40 mg/mL: Prescribing Information. Revised August 2023. Accessed July 9, 2026. https://www.triesencehcp.com/TRI-00002_Triesence_PI_web.pdf
6. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2025; Updated periodically.
7. 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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Policy History:

Type of Review	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Annual Review	Updated background information and service description to align with current prescribing information. Clarified that Triesence is for intraocular/intravitreal use. Updated Xipere criteria to require evidence of macular edema associated with uveitis. Updated Triesence criteria to reflect FDA-approved ophthalmic inflammatory disease indications and visualization during vitrectomy. Refined continuation criteria to distinguish repeat treatment for inflammatory disease from one-time/perioperative use for vitrectomy visualization. Added active ocular herpes simplex to Conditions not Covered for Triesence. Updated quantity limits to include dose volume, route, single-eye/single-dose language, and repeat treatment timing for Xipere. Coding reviewed: Added H20.10-H20.13, H20.20-H20.23, H35.81, H44.131-H44.139. Added H20.811-H20.819 to existing range H20.821- H20.819 and updated description. Removed H35.021-H35.029, H35.061- H35.069, H44.011-H44.013, H44.021-H44.023. Wording and formatting changes. Updated reference information and incorporated new policy template.	10/15/2026	10/21/2026
Annual Review	Minimal changes; word formatting. Coding reviewed: No changes.	9/5/2025	9/16/2025
Annual Review	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	Elevance Health's Medical Policy adoption.	10/30/2023	11/30/2023