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 drug approved by the Food and Drug Administration (FDA) for the treatment of suprachoroidal use.

Background Information

This document addresses the use of Xipere/Triesence (triamcinolone acetonide injectable suspension) for suprachoroidal use. Xipere/Triesence 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/Triesence (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/ Triesence 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/ Triesence 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/Triesence arm. The FDA label does not address re-treatment with Xipere/ Triesence, but current published data evaluated the use of two injections separated by 12 weeks (Yeh 2021).

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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	Triesence (triamcinolone acetonide)

ICD-10	Description
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
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, PosteriorPole
H30.031- H30.039	Focal chorioretinal inflammation, periphera[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
H30.91- H30.90	Unspecified chorioretinal inflammation [aka Retinitis NOS]
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)

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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.

Xipere/Triesence (triamcinolone acetonide injectable suspension)

Requests for Xipere/Triesence (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/Triesence (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.
   i. Approval duration: 1 month

Limits or Restrictions

A. 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	Limit
Xipere/Triesence (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.

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Reference Information

1.Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. URL: http://www.clinicalpharmacology.com. Updated periodically.

2. 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.

3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.

4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; 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.

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.

Policy History

Revision Type	Summary of Changes	P&T Approval Date	MPCC Approval Date
Policy Inception	Elevance Health's Medical Policy adoption.	10/30/2023	11/30/2023

Revised: 9/27/23