Effective Date **3/1/2022**
Next Review Date… **3/1/2023**
Coverage Policy Number **IP0371**

Triamcinolone Acetonide Ophthalmic

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Related Coverage Resources

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for **Xipere™ (triamcinolone acetonide)**.

Medical Necessity Criteria

Triamcinolone acetonide (Xipere) is considered medically necessary when the following are met:

1. **Macular Edema Associated with Uveitis.** Individual meets **ALL** of the following criteria (A, B, and C):
   A. Individual has non-infectious uveitis (i.e. pan, anterior, intermediate, or posterior)
   B. Individual has macular edema associated with non-infectious uveitis
   C. The medication is prescribed by, or in consultation with, an ophthalmologist

Coverage for triamcinolone acetonide (Xipere) varies across plans and may require the use of preferred products in addition to the medical necessity criteria listed above. Refer to the customer's benefit plan document for coverage details.

When coverage requires the use of preferred products, there is documentation of **ONE** of the following (A or B):

A. The individual has had inadequate efficacy to the number of covered alternatives according to the table below.

OR

B. The individual has a contraindication according to FDA label, significant intolerance, or is not a candidate* for the covered alternatives according to the table below.

**Note: Not a candidate due to being subject to a warning per the prescribing information (labeling), having a disease characteristic, individual clinical factor[s], other attributes/conditions, or is unable to administer and requires this dosage formulation*

Employer Group AND Individual and Family Plan Non-Preferred Products and Preferred Covered Alternatives by Drug List:

Non-Preferred Product	Standard / Performance	Value / Advantage	Cigna Total Savings	Legacy	Individual and Family Plans
Xipere (triamcinolone acetonide)	**ONLY** the following: • Triesence (triamcinolone acetonide)				

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Note: Receipt of sample product does not satisfy any criteria requirements for coverage.

Reauthorization Criteria

Xipere (triamcinolone acetonide) is considered medically necessary for continued use when initial criteria are met AND there is documentation of beneficial response.

- Example(s) of beneficial response: stabilization and/or improvement in best-corrected visual acuity (BCVA)

Authorization Duration

Initial approval duration: up to 6 months.

Reauthorization approval duration: up to 6 months.

Conditions Not Covered

Xipere (triamcinolone acetonide) is considered experimental, investigational or unproven for **ANY** other use.

Coding / Billing Information

Note: 1) This list of codes may not be all-inclusive.

2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
C9092	Injection, triamcinolone acetonide, suprachoroidal (Xipere), 1 mg

Background

OVERVIEW
Xipere (triamcinolone acetonide) injectable suspension 40 mg/mL is indicated for the treatment of macular edema associated with uveitis.[1]

Dosage and Administration
The recommended dose of Xipere is 4 mg (0.1 mL of the 40 mg/mL injectable suspension). Xipere is administered as a suprachoroidal injection using the SCS Microinjector®. The SCS Microinjector is a piston syringe and a needle approximately 1 mm in length (900-µm and 1100-µm needles are included) for conducting the suprachoroidal injection. The injection procedure should be carried out under aseptic conditions.[1]

Each Xipere package (microinjector syringe with vial adapter, 30-G x 900-µm needle, 30-G x 1,100-µm needle, and vial of triamcinolone acetonide injectable suspension 40 mg/mL) is single-dose and should only be used for the treatment of one eye.[1]

Efficacy
The efficacy of Xipere™ was assessed in a 6-month, randomized, multicenter, double-masked, sham-controlled study in patients with macular edema associated with anterior-, intermediate-, posterior-, or pan-uveitis. Patients were randomized to Xipere (n = 96) or control (n = 64) and treated at baseline and Week 12. The primary efficacy endpoint was the proportion of patients in whom best corrected visual acuity (BCVA) had improved by ≥ 15 letters from baseline after 24 weeks of follow-up. A statistically significantly greater proportion of patients treated with Xipere achieved a ≥ 15-letter improvement in BCVA than control patients (47% vs. 16%, respectively; $P < 0.01$) at Week 24.[1]

Other Therapy
Topical, periocular, and systemic corticosteroids are the main therapy for uveitis. Triesence™ (triamcinolone acetonide injectable suspension, 40 mg/mL) is indicated for treatment of uveitis, among other conditions, unresponsive to topical corticosteroids. The recommended dose of Triesence for ophthalmic diseases is 4 mg administered intravitreally under controlled aseptic conditions with subsequent dosage as needed over the course of treatment.[2]

Corticosteroid intravitreal implants are also available for the treatment of uveitis. Retisert® (fluocinolone acetonide 0.59 mg intravitreal implant) is indicated for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye. Retisert is implanted into the posterior segment of the affected eye through a pars plana incision. Retisert is designed to release fluocinolone acetonide at a nominal initial rate of 0.6 mcg/day, decreasing over the first month to a steady state between 0.3 to 0.4 mcg/day over approximately 30 months. Retisert may be replaced when uveitis recurs.[3] Ozurdex® (dexamethasone intravitreal implant) is indicated for the treatment of non-infectious uveitis affecting the posterior segment of the eye and also for the treatment of diabetic macular edema and macular edema following branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO). Ozurdex is an intravitreal implant containing dexamethasone 0.7 mg in the Novadur® solid polymer drug delivery system. The intravitreal injection procedure should be carried out under controlled aseptic conditions. Ozurdex is preloaded into a single-use applicator to facilitate injection of the rod-shaped implant directly into the vitreous.[4] Yutiq™ (fluocinolone acetonide 0.18 mg intravitreal implant) is indicated for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye. Yutiq is a non-bioerodible intravitreal implant in a drug delivery system containing 0.18 mg fluocinolone acetonide. The implant is designed

to release fluocinolone acetonide at an initial rate of 0.25 mcg/day, and lasting 36 months. Yutiq is supplied in a sterile single-dose preloaded applicator that can be administered directly into the vitreous in the physician's office under aseptic conditions.[5]

References

1. Xipere [package insert]. Alpharetta, GA; Clearside Biomedical, Inc; October 2021. Accessed October 2021.
2. Triesence [package insert]. Fort Worth, TX; Alcon Laboratories, Inc; December 2016. Accessed December 2021.
3. Retisert [package insert] Rochester, NY; Bausch & Lomb, Incorporated; May 2011. Accessed December 2021.
4. Ozurdex [package insert] Madison, NJ Allergan USA, Inc; October 2020. Accessed December 2021.
5. Yutiq [package insert] Watertown, MA; EyePoint Pharmaceuticals US, Inc; May 2021. Accessed December 2021.