CareSource Rx Innovations

# PHARMACY POLICY STATEMENT
## Marketplace

| DRUG NAME | Xipere (triamcinolone) |
|---|---|
| BILLING CODE | J3490 |
| BENEFIT TYPE | Medical |
| SITE OF SERVICE ALLOWED | Office |
| STATUS | Prior Authorization Required |

Xipere, approved by the FDA in 2021, is an injectable suspension formulation of triamcinolone acetonide, indicated for the treatment of macular edema associated with uveitis. It is injected into the suprachoroidal space to deliver the medication to the choroid and retina at the back of the eye. Xipere is currently the only FDA approved medication administered by this particular route and the first specifically for macular edema associated with uveitis. It was approved based on results of the phase 3 PEACHTREE trial. Xipere will compete with the intravitreal injectable, Triesence, and with the intravitreal implants, i.e., Retisert, Ozurdex, and Yutiq.
Uveitis is an inflammation of the uvea (middle layer of the eye). It can be infectious or non-infectious. Non-infectious uveitis (NIU) is often associated with inflammatory conditions such as rheumatoid arthritis. Approximately one-third of uveitis patients develop uveitic macular edema, a build-up of fluid in the macula, the area of the retina responsible for central vision.
Suprachoroidal administration is a more targeted technique which has shown to lessen the risk of the ocular adverse effects of intravitreal corticosteroids and systemic adverse effects of oral corticosteroids.

Xipere (triamcinolone) will be considered for coverage when the following criteria are met:

## Uveitic Macular Edema

For **initial** authorization:
1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with an ophthalmologist; AND
3. Member has a diagnosis of non-infectious uveitis (pan, anterior, intermediate, or posterior); AND
4. Member has a diagnosis of macular edema associated with uveitis; AND
5. Documentation of best corrected visual acuity (BCVA) at baseline; AND
6. Member does not have any active or suspected ocular or periocular infections.
7. **Dosage allowed/Quantity limit:** 4 mg (0.1mL) via suprachoroidal injection every 6 months (per eye)

***If all the above requirements are met, the medication will be approved for 3 months.***

For **reauthorization**:
1. Chart notes must show improved or stabilized visual acuity following treatment and/or reduction from baseline in central subfield thickness (CST); AND
2. At least 6 months have elapsed between treatments.

***If all the above requirements are met, the medication will be approved for an additional 12 months.***

**CareSource considers Xipere (triamcinolone) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.**

| DATE | ACTION/DESCRIPTION |
|---|---|
| **11/10/2021** | New policy for Xipere created. |

References:


1. Xipere [prescribing information]. Clearside Biomedical, Inc; 2021.
2. 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;127(7):948-955. doi:10.1016/j.ophtha.2020.01.006
3. Price KW, Albini TA, Yeh S. Suprachoroidal Injection of Triamcinolone- Review of a Novel Treatment for Macular Edema Caused by Noninfectious Uveitis. *US Ophthalmic Rev*. 2020;13(2):76-79. doi:10.17925/usor.2020.13.2.76
4. Khurana RN, Merrill P, Yeh S, et al. Extension study of the safety and efficacy of CLS-TA for treatment of macular oedema associated with non-infectious uveitis (MAGNOLIA) [published online ahead of print, 2021 Mar 12]. *Br J Ophthalmol*. 2021;bjophthalmol-2020-317560. doi:10.1136/bjophthalmol-2020-317560
5. Singer MA, Merrill P, Yeh S, Hall C, Kapik B, Ciulla TA. Suprachoroidal CLS-TA versus Rescue Therapies for the Treatment of Uveitic Macular Edema: A Post Hoc Analysis of PEACHTREE [published online ahead of print, 2021 Nov 6]. *Clin Exp Ophthalmol*. 2021;10.1111/ceo.14024. doi:10.1111/ceo.14024
6. Merrill PT, Henry CR, Nguyen QD, Reddy A, Kapik B, Ciulla TA. Suprachoroidal CLS-TA with and without Systemic Corticosteroid and/or Steroid-Sparing Therapy: A Post-Hoc Analysis of the Phase 3 PEACHTREE Clinical Trial [published online ahead of print, 2021 Aug 18]. *Ocul Immunol Inflamm*. 2021;1-8. doi:10.1080/09273948.2021.1954199


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