

Xipere® (triamcinolone acetonide injectable suspension)

(Suprachoroidal)

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I. Length of Authorization

Coverage will be provided for 12 weeks and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Xipere 40 mg/mL single-dose vial: 2 vials every 12 weeks

B. Max Units (per dose and over time) [HCPCS Unit]:

- 8 billable units (8 mg) every 12 weeks

(Quantity Limits/Max units are based on administration to BOTH eyes)

III. Initial Approval Criteria

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

Universal Criteria ¹

- Patient is free of ocular and periocular infections, including but not limited to, active epithelial herpes simplex keratitis; **AND**
- Patient has not received any of the following sustained-release intravitreal corticosteroids:
 - Dexamethasone – within the prior 4 months (i.e., Ozurdex®)
 - Fluocinolone acetonide – within the prior 30 months (i.e., Retisert®) or 36 months (i.e., Iluvien®/Yutiq™); **AND**
- Patient's best corrected visual acuity (BCVA) is measured at baseline and periodically during treatment; **AND**
- Patient does not have untreated intraocular pressure or uncontrolled glaucoma; **AND**

Macular Edema † ¹⁻³

- Patient has macular edema related to a diagnosis of non-infectious uveitis (pan, anterior, intermediate, and/or posterior)

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Ⓢ Orphan Drug

IV. Renewal Criteria ¹

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the universal and indication-specific relevant criteria as identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: cataracts, increase in intraocular pressure, glaucoma, alterations in endocrine function (e.g., hypothalamic-pituitary-adrenal [HPA] axis suppression, Cushing's syndrome, hyperglycemia), etc.; **AND**
- Disease response as indicated by stabilization of visual acuity or improvement in best-corrected visual acuity (BCVA) score when compared to baseline.

V. Dosage/Administration

Indication	Dose
Macular Edema secondary to non-infectious uveitis	Administer Xipere (triamcinolone acetonide injectable suspension) as a suprachoroidal injection using the SCS Microinjector®. The recommended dose of Xipere is 4 mg (0.1 mL of the 40 mg/mL injectable suspension) and may be repeated every 12 weeks.

VI. Billing Code/Availability Information

HCPCS code:

- J3299 – Injection, triamcinolone acetonide (xipere), 1 mg; 1 billable unit = 1 mg

NDC:

- Xipere 40 mg/mL injectable suspension single-dose vial: 71565-0040-xx

VII. References

1. Xipere [package insert]. Alpharetta, GA; Clearside Biomedical, Inc; October 2021. Accessed July 2022.
2. Yeh S, Kurup SK, Wang RC, et al for the DOGWOOD Study Team. Suprachoroidal injection of triamcinolone acetonide, CLS-TA, for macular edema due to noninfectious uveitis - A Randomized, Phase 2 Study (DOGWOOD). *Retina*: Oct2019;39,10:1880-1888. doi: 10.1097/IAE.0000000000002279.
3. Efficacy and Safety of Suprachoroidal CLS-TA for Macular Edema Secondary to Noninfectious Uveitis: Phase 3 Randomized Trial. Yeh S, Khurana RN, Shah M, Henry CR, Wang RC, Kissner JM, Ciulla TA, Noronha G, PEACHTREE Study Investigators *Ophthalmology*, 127(7):948-955, 10 Jan 2020

Appendix 1 – Covered Diagnosis Codes

ICD-10	Diagnosis
H30.001	Unspecified focal chorioretinal inflammation right eye
H30.002	Unspecified focal chorioretinal inflammation left eye
H30.003	Unspecified focal chorioretinal inflammation bilateral
H30.009	Unspecified focal chorioretinal inflammation unspecified eye
H30.011	Focal chorioretinal inflammation, juxtapapillary right eye
H30.012	Focal chorioretinal inflammation, juxtapapillary left eye
H30.013	Focal chorioretinal inflammation, juxtapapillary bilateral
H30.019	Focal chorioretinal inflammation, juxtapapillary unspecified eye
H30.021	Focal chorioretinal inflammation of posterior pole right eye
H30.022	Focal chorioretinal inflammation of posterior pole left eye
H30.023	Focal chorioretinal inflammation of posterior pole bilateral
H30.029	Focal chorioretinal inflammation of posterior pole unspecified eye
H30.031	Focal chorioretinal inflammation, peripheral right eye
H30.032	Focal chorioretinal inflammation, peripheral left eye
H30.033	Focal chorioretinal inflammation, peripheral bilateral
H30.039	Focal chorioretinal inflammation, peripheral unspecified eye
H30.041	Focal chorioretinal inflammation, macular or paramacular right eye
H30.042	Focal chorioretinal inflammation, macular or paramacular left eye
H30.043	Focal chorioretinal inflammation, macular or paramacular bilateral
H30.049	Focal chorioretinal inflammation, macular or paramacular unspecified eye
H30.101	Unspecified disseminated chorioretinal inflammation right eye
H30.102	Unspecified disseminated chorioretinal inflammation left eye
H30.103	Unspecified disseminated chorioretinal inflammation bilateral
H30.109	Unspecified disseminated chorioretinal inflammation unspecified eye
H30.111	Disseminated chorioretinal inflammation of posterior pole right eye
H30.112	Disseminated chorioretinal inflammation of posterior pole left eye
H30.113	Disseminated chorioretinal inflammation of posterior pole bilateral
H30.119	Disseminated chorioretinal inflammation of posterior pole unspecified eye
H30.121	Disseminated chorioretinal inflammation, peripheral right eye
H30.122	Disseminated chorioretinal inflammation, peripheral left eye
H30.123	Disseminated chorioretinal inflammation, peripheral bilateral
H30.129	Disseminated chorioretinal inflammation, peripheral unspecified eye
H30.131	Disseminated chorioretinal inflammation, generalized right eye
H30.132	Disseminated chorioretinal inflammation, generalized left eye
H30.133	Disseminated chorioretinal inflammation, generalized bilateral

ICD-10	Diagnosis
H30.139	Disseminated chorioretinal inflammation, generalized unspecified eye
H30.90	Unspecified chorioretinal inflammation unspecified eye
H30.91	Unspecified chorioretinal inflammation right eye
H30.92	Unspecified chorioretinal inflammation left eye
H30.93	Unspecified chorioretinal inflammation bilateral
H35.81	Retinal edema

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at:

<https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC