

Xipere® (triamcinolone acetonide injectable suspension) (Suprachoroidal)

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I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 12 weeks.
- Renewal: Prior authorization may be renewed every 12 weeks thereafter.

II. Dosing Limits

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

- 72 billable units (72 mg; 2 vials) every 12 weeks

(Max Units are based on administration to BOTH eyes)

III. Initial Approval Criteria

Prior authorization validity is provided in the following conditions:

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

Universal Criteria ^{1,3}

- Member does not have any FDA labeled contraindications to the requested agent (e.g., ocular or periocular infections, etc.); **AND**
- Member has not received a sustained-release corticosteroid in the same eye; **AND**
- Member's best corrected visual acuity (BCVA) is measured at baseline and periodically during treatment; **AND**
- Member does not have untreated intraocular pressure or uncontrolled glaucoma; **AND**

Macular Edema † ¹⁻³

- Member 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

Prior authorization validity can be renewed based upon the following criteria:

- Member 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 ¹

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 36 mg/0.9 mL (40 mg/mL concentration) injectable suspension single-dose vial: 24208-0040-xx

VII. References

1. Xipere [package insert]. Bridgewater, NJ; Bausch & Lomb Americas Inc.; May 2025. Accessed May 2026.
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. Yeh S, Khurana RN, Shah M, et al; PEACHTREE Study Investigators. 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. doi: 10.1016/j.ophtha.2020.01.006.

Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL

applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	No: PA not a priority
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

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

ICD-10	Diagnosis
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
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)

The preceding information is intended for non-Medicare coverage determinations. 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 Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents:

<https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications, including any preceding information, may be applied 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.

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
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
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
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