Clinical Policy: Corticosteroids for Ophthalmic Injection (Xipere)

Reference Number: LA.PHAR.385
Effective Date:
Last Review Date: 05.09.23
Line of Business: Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Please note: This policy is for medical benefit

Description
The following are corticosteroids for ophthalmic injection requiring prior authorization: triamcinolone acetonide suprachoroidal injection (Xipere™).

FDA Approved Indication(s)
Xipere is indicated for the treatment of macular edema associated with uveitis.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of Louisiana Healthcare Connections® that corticosteroids for ophthalmic injection are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Macular Edema with Uveitis (must meet all)**:**
1. Diagnosis of macular edema associated with non-infectious uveitis;
2. Request is for Xipere;
3. Prescribed by or in consultation with an ophthalmologist;
4. Age ≥ 18 years;
5. Inadequate response to Triesence® intravitreal injection, if available, unless contraindicated or clinically significant adverse effects are experienced;
6. Dose does not exceed 4 mg (1 vial) per eye every 12 weeks.

Approval duration: 6 months (two injections per eye)

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: LA.PMN.53 for Medicaid.

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via Louisiana Healthcare Connections benefit or member has previously met initial approval criteria
2. Member is responding positively to therapy;
3. At least 12 weeks have passed since last treatment with Xipere;
4. Dose does not exceed 4 mg (1 vial) per eye.

Approval duration: 3 months (one implant or injection per eye)

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: LA.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – LA.PMN.53 for Medicaid, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

BRVO: branch retinal vein occlusion
CRVO: central retinal vein occlusion
DME: diabetic macular edema
FDA: Food and Drug Administration
VEGF: vascular endothelial growth factor

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
anti-VEGF agents (e.g., bevacizumab, Lucentis®, Eylea®)	**Macular Edema** Refer to prescribing information	Refer to prescribing information
systemic corticosteroids (e.g., prednisone)	**Uveitis** prednisone 5 – 60 mg/day PO in 1 – 4 divided doses	Varies
azathioprine (Azasan®, Imuran®)	**Uveitis** 1.5 – 2 mg/kg/day PO	2.5 mg/kg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
chlorambucil (Leukeran®)	**Uveitis** 0.2 mg/kg PO QD, then taper to 0.1 mg/kg PO QD or less	0.2 mg/kg/day
cyclophosphamide (Cytoxan®)	**Uveitis** 1 – 2 mg/kg/day PO	N/A
cyclosporine (Sandimmune®, Neoral®)	**Uveitis** 2.5 – 5 mg/kg/day PO in divided doses	5 mg/kg/day
methotrexate (Rheumatrex®)	**Uveitis** 7.5 – 20 mg/week PO	30 mg/week
mycophenolate mofetil (Cellcept®)	**Uveitis** 500 – 1,000 mg PO BID	3 g/day
tacrolimus (Prograf®)	**Uveitis** 0.1 – 0.15 mg/kg/day PO in 2 divided doses given for 12 weeks	N/A
intravitreal corticosteroids: Triesence (triamcinolone)	**All Indications** 4 mg injected intravitreally per affected eye	4 mg/eye

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications / Boxed Warnings

- Contraindication(s):
  - Xipere: ocular or periocular infections.
- Boxed warning(s): none reported

Appendix D: General Information

- In one study, intravitreal bevacizumab (1.25 mg) and the dexamethasone (DEX) (0.7 mg) implant were compared in a randomized, Phase II trial called the BEVORDEX study. 79 Forty-two eyes received intravitreal bevacizumab every 4 weeks, and 46 eyes received an intravitreal DEX (0.7 mg) implant every 16 weeks, with a when necessary (PRN) regimen for 12 months. The primary outcome of the study was to gain ten or more letters in the best-corrected distance visual acuity (BCVA) at 12 months, which was achieved in 40% of the bevacizumab-treated eyes and 41% of the DEX implant-treated group (P=0.99). The mean corneal refractive therapy (CRT) decrease was statistically significant between the groups, and the reduction was 122 µm in the bevacizumab group and 187 µm in the DEX implant group (P=0.015). The mean number of injections over 1 year was 8.6 for the bevacizumab group and 2.7 for the DEX implant group. Finally, in the DEX implant-treated eyes, 11% lost ten or more letters of the BCVA, which was due to cataracts in 4 of 5 cases; none lost ten letters in the bevacizumab-treated eyes.

- The POINT trial by Thorne et al. found no significant difference between intravitreal triamcinolone acetonide injection and intravitreal dexamethasone implant in terms of safety and efficacy for the treatment of uveitic macular edema.

V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
Triamcinolone (Xipere)	Macular edema associated with uveitis	4 mg (0.1 mL) administered as a suprachoroidal injection	One injection per eye every 12 weeks

VI. Product Availability

Drug Name	Availability
Triamcinolone (Xipere)	Injectable suspension in a single-dose vial: 40 mg/mL

VII. References

1. Xipere Prescribing Information. Alpharetta, GA: Clearside Biomedical, Inc.; October 2021. Available at: www.xipere.com. Accessed March 30, 2022.
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6. Gillies MC, Lim LL, Campain A, et al. A randomized clinical trial of intravitreal bevacizumab versus intravitreal dexamethasone for diabetic macular edema: the BEVORDEX study. Ophthalmology. 2014;121(12):247-324.
7. Lam WC, Albiani DA, Yoganathan P, et al. Real-world assessment of intravitreal dexamethasone implant (0.7 mg) in patients with macular edema: the CHROME study. Clin Ophthalmol. 2015 Jul 10;9:1255-68. doi: 10.2147/OPTH.S80500. eCollection 2015.
8. Sen HN, Albin TA, Burkholder BM, et al. Section 9: Uveitis and ocular inflammation. In: American Academy of Ophthalmology 2020-2021 Basic and Clinical Science Course. American Academy of Ophthalmology; 2020.
9. Dick AD, Rosenbaum JT, Al-Dhibi HA, et al. Guidance on noncorticosteroid systemic immunomodulatory therapy in noninfectious uveitis: Fundamentals Of Care for UveitiS (FOCUS) initiative. Ophthalmology. 2018; 125(5): 757-773.
10. 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. Opthalmology. 2020; 127(7): 948-955.

11. Thorne JE, Sugar EA, Holbrook JT, et al. Periocular triamcinolone vs. intravitreal triamcinolone vs. intravitreal dexamethasone implant for the treatment of uveitic macular edema: the PeriOcular vs. INTravitreal corticosteroids for uveitic macular edema (POINT) trial. Ophthalmology. 2019; 126(2): 283-295.

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

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

Reviews, Revisions, and Approvals	Date	LDH Approval Date
Policy created	05.09.23	

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. LHCC retains the right to change, amend or

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