Original Effective Date: 01/26/2022
Current Effective Date: 10/25/2023
Last P&T Approval/Version: 10/25/2023
Next Review Due By: 10/2024
Policy Number: C22222-A

Xipere (triamcinolone acetonide ocular inj)

PRODUCTS AFFECTED

Xipere (triamcinolone acetonide ocular inj)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Macular edema associated with uveitis

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. MACULAR EDEMA ASSOCIATED WITH UVEITIS:
1. Documented diagnosis of macular edema associated with anterior-, intermediate-, posterior-, or pan-uveitis
AND
2. Documentation of an inadequate response (appropriate trial period included), serious side effects, or contraindication to formulary topical glucocorticoids OR an intravitreal steroid (e.g., triamcinolone, dexamethasone) OR a systemic corticosteroid
AND
3. Documentation of member's baseline best-corrected visual acuity (BCVA) in order to measure efficacy.
AND
4. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to Xipere (triamcinolone acetonide ocular inj) include: ocular or periocular infections and hypersensitivity to triamcinolone or any component of this product]

CONTINUATION OF THERAPY:
A. MACULAR EDEMA ASSOCIATED WITH UVEITIS:
1. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
AND
2. Documentation of positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms [i.e., best-corrected visual acuity (BCVA) improvement since baseline or documented decrease in inflammation or pain]

DURATION OF APPROVAL:
Initial authorization: 6 months, Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:
Prescribed by or in consultation with a board-certified ophthalmologist or other specialist in uveal eye disease. [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:
18 years of age and older

QUANTITY:
4mg suprachoroidal injection at baseline and week 12 then as recommended by prescriber

PLACE OF ADMINISTRATION:
The recommendation is that suprachoroidal injection medications in this policy will be for pharmacy or medical benefit coverage and the suprachoroidal injection products be administered in a place of service that is a non-hospital facility-based location.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Suprachoroidal Injection

DRUG CLASS:

Ophthalmic Steroids

FDA-APPROVED USES:
Indicated for the treatment of macular edema associated with uveitis

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Macular edema is the buildup of fluid in the macula, which causes retinal swelling and distorted vision, and if left untreated, may lead to permanent vision loss. XIPERE™ is designed to treat macular edema associated with uveitis via suprachoroidal administration using the proprietary SCS Microinjector® developed by Clearside. Suprachoroidal administration is an innovative technique for delivering ocular therapies that may facilitate more targeted delivery of therapeutic agents to the retina and choroid.

The SCS Microinjector® offers unique access to the back of the eye where sight-threatening disease often occurs. It is designed to provide targeted and compartmentalized delivery and higher proportions of absorption relative to intravitreal injection (IVT). Targeted drug delivery via the suprachoroidal space (SCS®) may also limit corticosteroid exposure to the anterior segment with the potential to reduce the risk of certain adverse events, such as cataracts, intraocular pressure elevation and exacerbation of glaucoma, that are commonly associated with local delivery techniques.

Xipere was approved based on clinical trial results from the Phase 3 PEACHTREE trial (NCT02595398). Patients were treated at baseline and Week 12 with a single injection of 4 mg (0.1 mL) of Xipere. 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. Results indicate that 47% of patients in the Xipere arm met the endpoint versus 16% in the control arm (P <0.01). The most common adverse reactions reported by greater than or equal to 10% of patients and at a rate greater than control included elevated intraocular pressure and eye pain.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Xipere (triamcinolone acetonide ocular inj) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications Xipere (triamcinolone acetonide ocular inj) include: ocular or periocular infections and hypersensitivity to triamcinolone or any component of this product.

OTHER SPECIAL CONSIDERATIONS:
Suprachoroidal injection is performed under aseptic conditions

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

HCPCS CODE	DESCRIPTION
J3299	Injection, triamcinolone acetonide (xipere), 1 mg

AVAILABLE DOSAGE FORMS:
Xipere SUSP 40MG/ML single-dose vial

REFERENCES

1. Xipere (triamcinolone) [prescribing information]. Alpharetta, GA: Clearside Biomedical Inc; February 2022.
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3. Viral S. Kansara, Leroy W. Muya, Thomas A. Ciulla; Evaluation of Long-Lasting Potential of Suprachoroidal Axitinib Suspension Via Ocular and Systemic Disposition in Rabbits. Trans. Vis. Sci. Tech. 2021;10(7):19. doi: https://doi.org/10.1167/tvst.10.7.19.
4. Chiang B, Jung JH, Prausnitz MR. The suprachoroidal space as a route of administration to the posterior segment of the eye. Adv Drug Deliv Rev. 2018;126:58-66. doi:10.1016/j.addr.2018.03.001.
5. Moisseiev E, Loewenstein A, Yiu G. The suprachoroidal space: from potential space to a space with potential. Clin Ophthalmol. 2016;10:173-178. Published 2016 Jan 25. doi:10.2147/OPTH.S89784
6. Singer, M. A., Merrill, P., Yeh, S., Hall, C., Kapik, B., & Ciulla, T. A. (2022). Suprachoroidal triamcinolone acetonide versus rescue therapies for the treatment of uveitic macular oedema: A post hoc analysis of PEACHTREE. Clinical & experimental ophthalmology, 50(1), 23–30. https://doi.org/10.1111/ceo.14024
7. Price, K. W., Albini, T. A., & Yeh, S. (2020). Suprachoroidal Injection of Triamcinolone- Review of a Novel Treatment for Macular Edema Caused by Noninfectious Uveitis. US ophthalmic review, 13(2), 76–79. https://doi.org/10.17925/usor.2020.13.2.76

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information	Q4 2023
REVISION- Notable revisions: Required Medical Information Continuation of Therapy HCPCS Code and Description References	Q1 2023
Q2 2022 Established tracking in new format	Historical changes on file