SAMPLE LETTER OF MEDICAL NECESSITY\*

**\*NOTE: This sample letter is provided for informational purposes only. It is the responsibility of the healthcare professional, as appropriate, to determine the correct diagnosis, treatment protocol, and content of all such letters and related forms for each individual patient. Bausch + Lomb does not guarantee coverage or reimbursement for the product. Please note that some payers may have specific forms that must be completed to request prior authorization or to document medical necessity.**

[INSERT PHYSICIAN LETTERHEAD]

|  |  |
| --- | --- |
| [Contact Name of Medical Director/Payer Representative] | [Patient Name] |
| [Name of Health Insurance Company] | [Group/Policy #] |
| [Address] | [Claim #] |
| [City, State ZIP] | [Date of Service] |

Dear [INSERT PAYER CONTACT NAME or DEPARTMENT]:

I am writing on behalf of my patient, [PATIENT NAME], to [REQUEST PRIOR AUTHORIZATION/REQUEST APPROVAL/DOCUMENT MEDICAL NECESSITY] for treatment with XIPERE. This letter serves to document that [PATIENT NAME] has a diagnosis of [DIAGNOSIS] and treatment with XIPERE is medically necessary as prescribed.

**XIPERE (triamcinolone acetonide injectable suspension) 40 mg/mL key information:**

* FDA-approved for the treatment of macular edema associated with uveitis1
* Only drug that is delivered via injection into the suprachoroidal space (SCS)2
* An innovative delivery system that delivers drug to the target tissues while minimizing exposure to nontarget tissues3
* Evaluated in multiple clinical studies (DOGWOOD, PEACHTREE, MAGNOLIA, AZALEA), including controlled registrational studies reported in the XIPERE Prescribing Information.1 According to the American Academy of Ophthalmology, these studies represent Level-I clinical evidence4
* Real-world performance confirmed via data from the IRIS® registry5

**In June 2024, “Expert Panel Guidance for Suprachoroidal Space (SCS) Injection Technique” was published in *Retina®, The Journal of Retinal and Vitreous Diseases***

* The guidance highlights rationale and support for SCS injections, including2:
	+ Potential benefits relative to other intraocular delivery methods
	+ Opportunity for targeted delivery of high levels of injectate directly to affected chorioretinal tissues
	+ Use in the in-office site of care
* The guidance also highlighted XIPERE key information2:
	+ XIPERE (triamcinolone acetonide suspension administered via SCS injection) is the first and only therapy approved for suprachoroidal use, with an indication for uveitic macular edema
	+ Clinical trials support the efficacy and safety of XIPERE and SCS administration in this patient population
	+ Safety evaluation of XIPERE has shown low IOP-related adverse event (AE) rates with no serious ocular AEs out to 24 weeks
	+ Trials assessing SCS injection were completed in the office setting, and the data support the efficacy and safety of triamcinolone acetonide administered via SCS injection

I encourage you to review this newly published guidance using the link or PDF attachment provided below.

|  |  |
| --- | --- |
| [RETINA (lww.com)](https://journals.lww.com/retinajournal/fulltext/2024/06000/suprachoroidal_space_injection_technique__expert.1.aspx) |  |

**Patient Medical History and Diagnosis**

[PATIENT NAME] is a [AGE]‐year‐old [MALE/FEMALE] diagnosed with [DIAGNOSIS]. [NAME OF PATIENT] has been in my care since [DATE]. As a result of [DIAGNOSIS], my patient [ENTER BRIEF DESCRIPTION OF PATIENT HISTORY]. Additionally, [PATIENT] has tried [PREVIOUS THERAPIES] and [LIST OUTCOMES]. The attached medical records document [PATIENT NAME]’s clinical condition and medical necessity for XIPERE as described below.

[INSERT ALL RELEVANT MEDICALLY NECESSARY CLINICAL DETERMINATIONS]

**Treatment Rationale**

[NOTE: EXERCISE YOUR MEDICAL JUDGMENT AND DISCRETION WHEN CHARACTERIZING THE PATIENT’S MEDICAL CONDITION. YOU MAY WANT TO INCLUDE:

* PATIENT’S CONDITION AND HISTORY
* PREVIOUS THERAPIES THE PATIENT HAS UNDERGONE
* PATIENT’S RESPONSE TO THESE THERAPIES
* BRIEF DESCRIPTION OF THE PATIENT’S RECENT SYMPTOMS AND CONDITIONS
* SUMMARY OF YOUR PROFESSIONAL OPINION OF THE PATIENT’S LIKELY PROGNOSIS OR DISEASE PROGRESSION WITHOUT TREATMENT WITH XIPERE]

**Enclosures** (Attach as appropriate): FDA approval letter, Prescribing Information (PI), clinic notes & labs

Based on the above clinical details, I am confident that you will agree that XIPERE (triamcinolone acetonide injectable suspension) 40 mg/mL is medically necessary for this patient. The plan of treatment is to start the patient on XIPEREand monitor the patient’s progress.

On behalf of [PATIENT NAME], I am requesting approval for use, coverage, and subsequent reimbursement of XIPERE. If you have any further questions regarding this matter, please do not hesitate to call me at [PHYSICIAN TELEPHONE NUMBER]. Thank you for your prompt attention to this matter.

Sincerely,

[PHYSICIAN NAME], [DEGREE INITIALS]

[PROVIDER IDENTIFICATION NUMBER]

**Indication**

XIPERE® (triamcinolone acetonide injectable suspension) for suprachoroidal use is a corticosteroid indicated for the treatment of macular edema associated with uveitis.

**IMPORTANT SAFETY INFORMATION**

Patients should be monitored following injection for elevated intraocular pressure. See Dosage and Administration instructions in full Prescribing Information.

* XIPERE® is contraindicated in patients with **active or** **suspected ocular or periocular infections** including most viral diseases of the cornea and conjunctiva, including active epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella, mycobacterial infections, and fungal diseases.
* XIPERE® is contraindicated in patients with known **hypersensitivity to triamcinolone acetonide** or any other components of this product.
* Use of corticosteroids may produce cataracts, increased intraocular pressure, and glaucoma. Use of corticosteroids may enhance the establishment of secondary ocular infections due to bacteria, fungi, or viruses, and should be used cautiously in patients with a history of ocular herpes simplex.
* Hypothalamic-pituitary-adrenal (HPA) axis suppression, Cushing’s syndrome, and hyperglycemia can occur following administration of a corticosteroid. Monitor patients for these conditions with chronic use.
* In controlled studies, the most common ocular adverse reactions were increased ocular pressure, non-acute (14%), eye pain, non-acute (12%), cataract (7%), increased intraocular pressure, acute (6%), vitreous detachment (5%), injection site pain (4%), conjunctival hemorrhage (4%), visual acuity reduced (4%), dry eye (3%), eye pain, acute (3%), photophobia (3%), and vitreous floaters (3%), and in 2% of patients: uveitis, conjunctival hyperaemia, punctate keratitis, conjunctival oedema, meibomianitis, anterior capsule contraction, chalazion, eye irritation, eye pruritus, eyelid ptosis, photopsia, and vision blurred.

The most common non-ocular adverse event was headache (5%).

* Corticosteroids should be used during pregnancy or nursing only if the potential benefit justifies the potential risk to the fetus or nursing infant.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program) or call 1-800-FDA-1088.

**Please** **click here for** **full Prescribing Information.**

**References: 1.** XIPERE®. Prescribing Information. Bausch & Lomb Incorporated. **2.** Wykoff C et al. Suprachoroidal space injection technique: expert panel guidance. *Retina*. 2024;44:939-949. **3.** Chiang B, Jung J, Prausnitz M. The suprachoroidal space as a route of administration to the posterior segment of the eye. *Adv Drug Deliv Rev*. 2018;126:58-66. **4.** Smith JR et al. Treatment of noninfectious uveitic macular edema with periocular and intraocular corticosteroid therapies: a report by the American Academy of Ophthalmology. 2024;1-14. doi.org/10.1016/j.ophtha.2024.02.019 **5.** Singer M et al. Presented at: 47th Annual Macula Society Meeting; February 7-10, 2024; Palm Springs, California.