SAMPLE LETTER OF MEDICAL NECESSITY\*

(\*Please note that this template is intended only as an example and should be customized with patient-specific details and information utilizing your medical judgement prior to submission to the payer.)

# [Insert physician letterhead]

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

Dear **[insert name of contact or department]**:

I am writing on behalf of my patient, **[insert patient name]**, to document medical necessity and request continuation of coverage for treatment with XIIDRA® (lifitegrast ophthalmic solution) 5%. This letter serves to document that **[insert patient name]** has been diagnosed with dry eye disease (DED) and continuation of treatment with XIIDRA® is medically necessary as prescribed. On behalf of the patient, I am requesting approval for continued use and subsequent payment for the treatment.

My patient has previously attempted other treatments for DED, but those trials have failed due either to inadequate efficacy or lack of tolerability as set forth in the attached medical records. Furthermore, this patient has been using XIIDRA® to treat their DED since **[insert date]** and I deem it medically necessary for this patient to continue treatment. Any change to the current dry eye treatment therapy for this patient may result in unwanted burden to the patient and a potential undesired impact on the quality of therapeutic care they currently experience.

XIIDRA® is an FDA-approved drug indicated for the treatment of the signs and symptoms of DED.1 DED is a cycle driven by inflammation, desiccation stress, and tissue damage, all of which cause loss of ocular surface homeostasis.2-4 As such, it is a chronic, self-perpetuating, and progressive condition.2 T cell-mediated inflammation is central to DED pathogenesis and progression.5,6 XIIDRA® is the only DED medication which is designed to target both active and inactive T cells.1 These actions result in reduction of inflammation and improves the signs and symptoms of DED.1,† It is for these reasons I have specifically prescribed XIIDRA® for this patient’s treatment.

Along with this letter, I have enclosed a copy of my patient’s medical records.

***[Provide a description of the patient's medical condition, history, and treatment history, including current treatment with XIIDRA®, if applicable. Highlight any relevant clinical data, test results, or specialist recommendations supporting the use of the medication.]***

***[Explain why alternative treatments are not sufficient or appropriate for the patient's condition, emphasizing the potential risks or lack of efficacy compared to the prescribed medication.]***

***[Discuss the potential consequences of denying coverage for the medication, and for discontinuation of treatment with XIIDRA® (if applicable), such as exacerbation of symptoms, decreased quality of life, or increased healthcare costs due to complications.]***

***[If applicable, include any relevant insurance policy language or guidelines that support coverage for the medication.]***

Based on the above facts, I am confident that you will agree that it is medically necessary for my patient to continue treatment with XIIDRA®. If you have any further questions regarding this matter, please do not hesitate to call me at **[insert telephone number]**.

Thank you for your prompt attention to this matter. Sincerely,

# [Insert Provider Name and participating provider number]

†XIIDRA® reduced symptoms of eye dryness based on EDS (eye dryness score) at 2 weeks in 2 out of 4 studies, with improvements observed at 6 and 12 weeks in all 4 studies and reduced signs of dry eye in 3 out of 4 studies at 12 weeks.1

# Indication

Xiidra® (liﬁtegrast ophthalmic solution) 5% is indicated for the treatment of signs and symptoms of dry eye disease (DED).

# Important Safety Information

* Xiidra is contraindicated in patients with known hypersensitivity to liﬁtegrast or to any of the other ingredients.
* In clinical trials, the most common adverse reactions reported in 5-25% of patients were instillation site irritation, dysgeusia and reduced visual acuity. Other adverse reactions reported in 1% to 5% of the patients were blurred vision, conjunctival hyperemia, eye irritation, headache, increased lacrimation, eye discharge, eye discomfort, eye pruritus and sinusitis.
* To avoid the potential for eye injury or contamination of the solution, patients should not touch the tip of the single-use container to their eye or to any surface.
* Contact lenses should be removed prior to the administration of Xiidra and may be reinserted 15 minutes following administration.
* Safety and efﬁcacy in pediatric patients below the age of 17 years have not been established.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

# Please click here for [Full Prescribing Information](https://pi.bausch.com/globalassets/pdf/packageinserts/pharma/xiidra-prescribing-information.pdf) for XIIDRA.

**References: 1.** XIIDRA®. Prescribing Information. Bausch & Lomb, Inc. **2.** Bron AJ, de Paiva CS, Chauhan SK, et al. TFOS DEWS II pathophysiology report [published correction appears in *Ocul Surf.* 2019;17(4):842]. *Ocul Surf.* 2017;15(3):438-510. doi:10.1016/j.jtos.2017.05.011 **3.**

Pflugfelder SC, de Paiva CS. The pathophysiology of dry eye disease: what we know and future directions for research. *Ophthalmology*. 2017;124(11S):S4-S13. doi:10.1016/j.ophtha.2017.07.010 **4.** Zhang R, Pandzic E, Park M, Wakefield D, Di Girolamo N. Inducing dry eye disease using a custom engineered desiccation system: impact on the ocular surface including keratin-14-positive limbal epithelial stem cells. *Ocul Surf*. 2021;21:145-159. doi:10.1016/j.jtos.2021.04.006 **5.** Pflugfelder SC, Stern M, Zhang S, Shojaei A. LFA-1/ICAM-1 interaction as a therapeutic target in dry eye disease. *J Ocul Pharmacol Ther.* 2017;33(1)5-12. doi:10.1089/jop.2016.0105 **6.** Periman LM, Perez VL, Saban DR, Lin MC, Neri P. The immunological basis of dry eye disease and current topical treatment options. *J Ocul Pharmacol Ther.* 2020;36(3):137-146. doi:10.1089/jop.2019.0060

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