Sample Tier Exception Letter*

***Please note:** This template is intended only as an example and should be customized with patient-specific details and information, along with any other modifications you deem necessary in your medical judgment prior to submission to the payer.

[INSERT PHYSICIAN LETTERHEAD]

[Medical Director]
[Insurance Company]
[Address]
[City, State ZIP]

RE: [Patient Name]
[Patient's Date of Birth]
[Policy Number]
[Claim Number]

Dear **[Medical Director]**:

I am writing to request a tiering exception of XIIDRA® (lifitegrast ophthalmic solution) 5% for my patient, **[Patient Name]**, who is currently a member of **[Name of health plan]**. XIIDRA® is medically appropriate and necessary for this patient, who has been diagnosed with dry eye disease (DED).†

The reason I am requesting a tiering exception is because the cost associated with the XIIDRA® assigned tier presents a financial burden to my patient. That financial burden prevents my patient from utilizing a medication that will help treat DED. I am requesting that XIIDRA® be covered for my patient at the same cost as the lowest preferred branded agent on your formulary. XIIDRA® has already been approved, **[PA Approval number]**. My patient has 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.

Along with this letter, I have enclosed a copy of my patient's medical records and a letter of medical necessity. This letter describes why XIIDRA® is medically necessary for my patient's care over the preferred drugs listed in the plan's formulary. To summarize, 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 homeostasis.[2-4] T cell-mediated inflammation is central to DED pathogenesis and progression.[5,6] XIIDRA® is designed to inhibit inflammation by inhibiting both active and inactive T cells to address the signs and symptoms of DED.[1,7,‡]

Based on the patient's history, condition, and the published data supporting use of XIIDRA®, I consider XIIDRA® to be the best option in successfully treating my patient's DED. Please contact me to answer any pending questions.

Sincerely,

[Physician's name and signature]

[Physician's medical specialty] [Physician's NPI]

[Physician's practice name]

[Phone #] [Fax #]

Enclosures: ***[Medical records, photo(s), Letter of Medical Necessity, statement of financial hardship, case number, written response to denial]***

NPI, National Provider Identifier
†Include patient's medical records and supporting documentation, including clinical evaluation, scoring forms, and photos of affected areas.
‡The exact mechanism of action of lifitegrast in dry eye disease is not known.

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 or call 1-800-FDA-1088.

Please click here for Full Prescribing Information for XIIDRA.

References: 1. XIIDRA®. Prescribing Information. Bausch & Lomb, Inc; 2023. **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 **7.** Perez VL, Pflugfelder SC, Zhang S, Shojaei A, Haque R. Lifitegrast, a novel integrin antagonist for treatment of dry eye disease. *Ocul Surf.* 2016;14(2):207-215. doi:10.1016/j.jtos.2016.01.001