**Sample Letter of Medical Necessity\***

\*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 name of medical director/payer representative/department]**,

I am writing on behalf of my patient, **[Patient name]**, to **[Document medical necessity/request medical exception]** for treatment with VYZULTA® (latanoprostene bunod ophthalmic solution), 0.024%. This letter serves to document that **[Patient name]** has a diagnosis of **[Diagnosis]**, and treatment with VYZULTA is medically necessary as prescribed.

VYZULTA is FDA-approved to lower intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.1 There is currently no generic for VYZULTA.

VYZULTA works differently than other prostaglandin analogues (PGAs), as it is the only PGA that delivers nitric oxide as part of a dual MOA with latanoprost acid.1,2

IOP is determined by the production and drainage of aqueous humor and is the only modifiable risk factor for glaucoma progression.3 Aqueous humor drains primarily via the trabecular meshwork (TM), which is responsible for up to 80% of aqueous outflow humor, and the uveoscleral outflow pathway.4 Nitric oxide promotes cellular relaxation in the trabecular meshwork to increase outflow while nitric oxide deficiency is believed to play a role in chronic TM contraction.2 VYZULTA is thought to lower IOP by increasing outflow of aqueous humor through both the trabecular meshwork and uveoscleral outflow pathways.1,2

**Key VYZULTA efficacy data:**

* In the phase 2 dose-ranging VOYAGER study, VYZULTA significantly outperformed Xalatan (latanoprost 0.005%) in mean diurnal IOP reduction from baseline5:
	+ At Day 28, VYZULTA delivered a 34.6% mean IOP reduction vs 29.8% mean IOP reduction with Xalatan
	+ At Day 28, 44% more patients achieved an IOP of ≤18 mmHg while taking VYZULTA as compared to those taking Xalatan (69% vs 48%, respectively)
* In the 2 pivotal phase 3 studies (APOLLO and LUNAR), VYZULTA provided significantly greater IOP reduction from baseline compared with timolol 0.5%6-8
	+ Up to 9.1 mmHg IOP reduction from baseline
	+ >30% mean diurnal IOP reduction across all tested timepoints
* In real-world study evidence, VYZULTA demonstrated9,10:
	+ 41% mean IOP reduction from baseline in first-line (new-to-treatment) patients with high baseline IOP
	+ 22% mean IOP reduction from baseline in first-line (new-to-treatment) patients with low baseline IOP
	+ 25% mean IOP reduction for all patients who switched to VYZULTA from existing PGA treatment

**Key VYZULTA tolerability data1,11:**

* In phase 3 studies, VYZULTA had a low incidence of hyperemia
* Ocular AEs occurring in ≥2% of study eyes (safety population) included conjunctival hyperemia (5.9%), eye irritation (4.6%), eye pain (3.6%), ocular hyperemia (2.0%), instillation site pain (2.0%)
* <1% of patients discontinued due to any ocular AE

Summary of Patient’s History **[NOTE: Exercise your medical judgement and discretion when characterizing the patient’s medical condition. You may want to include:**

* **Patient’s condition, symptoms, and history**
* **Previous therapies the patient has undergone**
* **Patient’s response to these therapies**
* **Summary of your professional opinion of patients’ likely prognosis of disease progression without or if discontinued from treatment with VYZULTA]**

Based on the above clinical details, I am confident that you will agree that VYZULTA is medically necessary for this patient. On behalf of **[Patient name]**, I am requesting approval for use and coverage for VYZULTA. 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**

VYZULTA® (latanoprostene bunod ophthalmic solution), 0.024% is indicated for the reduction of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.

**IMPORTANT SAFETY INFORMATION**

* Increased pigmentation of the iris and periorbital tissue (eyelid) can occur. Iris pigmentation is likely to be permanent
* Gradual changes to eyelashes, including increased length, increased thickness, and number of eyelashes, may occur. These changes are usually reversible upon treatment discontinuation
* Use with caution in patients with a history of intraocular inflammation (iritis/uveitis). VYZULTA should generally not be used in patients with active intraocular inflammation
* Macular edema, including cystoid macular edema, has been reported during treatment with prostaglandin analogs. Use with caution in aphakic patients, in pseudophakic patients with a torn posterior lens capsule, or in patients with known risk factors for macular edema
* There have been reports of bacterial keratitis associated with the use of multiple-dose containers of topical ophthalmic products that were inadvertently contaminated by patients
* Contact lenses should be removed prior to the administration of VYZULTA and may be reinserted
15 minutes after administration
* Most common ocular adverse reactions with incidence ≥2% are conjunctival hyperemia (6%), eye irritation (4%), eye pain (3%), and instillation site pain (2%)

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**](https://pi.bausch.com/globalassets/pdf/PackageInserts/Pharma/vyzulta-prescribing-information.pdf?utm_source=bing&utm_medium=cpc&utm_campaign=22_Vyzulta_HCP_Branded_Brand&utm_content=Vyzulta_General_Exact&utm_term=vyzulta) **for full Prescribing Information.**

**References: 1.** VYZULTA. Prescribing Information. Bausch & Lomb Inc. **2.** Cavet ME, Vollmer TR, Harrington KL, VanDerMeid K, Richardson ME. Regulation of endothelin-1-induced trabecular meshwork cell contractility by latanoprostene bunod. *Invest Ophthalmol Vis Sci*. 2015;56(6):4108-4116. **3.** American Academy of Ophthalmology. Primary open-angle glaucoma preferred practice pattern®. November 2020. Accessed December 30, 2024.https://www.aao.org/education/preferred-practice-pattern/ primary-open-angle-glaucoma-ppp **4.** Winkler NS, Fautsch MP. Effects of prostaglandin analogues on aqueous humor outflow pathways. *J Ocul Pharmacol Ther*. 2014;30(2-3):102-109 **5.** Weinreb RN, Ong T, Scassellati Sforzolini B, Vittitow JL, Singh K, Kaufman PL; VOYAGER Study Group. A randomised, controlled comparison of latanoprostene bunod and latanoprost 0.005% in the treatment of ocular hypertension and open-angle glaucoma: the VOYAGER study. *Br J Ophthalmol.* 2015;99(6):738-745. **6.** Weinreb RN, Scassellati Sforzolini B, Vittitow J, Liebmann J. Latanoprostene bunod 0.024% versus timolol maleate 0.5% in subjects with open-angle glaucoma or ocular hypertension: the APOLLO study. *Ophthalmology*. 2016;123(5):965-973. **7.** Medeiros FA, Martin KR, Peace J, Scassellati Sforzolini B, Vittitow JL, Weinreb RN. Comparison of latanoprostene bunod 0.024% and timolol maleate 0.5% in open-angle glaucoma or ocular hypertension: the LUNAR study. *Am J Ophthalmol*. 2016;168:250-259. **8.** Kaufman PL. Latanoprostene bunod ophthalmic solution 0.024% for IOP lowering in glaucoma and ocular hypertension. *Expert Opin Pharmacother*. 2017;18(4):433-444. **9.** Okeke CO, Burstein ES, Trubnik V, et al. Retrospective chart review on real-world use of latanoprostene bunod 0.024% in treatment-naïve patients with open-angle glaucoma. *Ophthalmol Ther*. 2020;9(4):1041-1053. **10.** Okeke CO, Cothran NL, Brinkley DA, Rahmatnejad K, Rodiño FJ, Deom JE. Latanoprostene bunod 0.024% in patients with open-angle glaucoma switched from prior pharmacotherapy: a retrospective chart review. *Clin Ophthalmol*. 2024;18:409-422. **11.** Weinreb RN, Liebmann JM, Martin KR, Kaufman PL, Vittitow JL. Latanoprostene bunod 0.024% in subjects with open-angle glaucoma or ocular hypertension: pooled phase 3 study findings. *J Glaucoma*. 2018;27(1):7-15.