

Sample Letter of Medical Necessity for XDEMZY® (lotilaner ophthalmic solution) 0.25%

This sample letter is for informational purposes only.

Health plan requirements may vary. Please confirm specific information required by your patient's health plan to ensure you are providing accurate and complete information.

Note: When preparing the actual letter, use your professional/practice letterhead and refer to the sample on the next page.

INDICATION

XDEMZY is indicated for the treatment of *Demodex* blepharitis.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Risk of Contamination: Do not allow the tip of the dispensing container to contact the eye, surrounding structures, fingers, or any other surface in order to minimize contamination of the solution. Serious damage to the eye and subsequent loss of vision may result from using contaminated solutions.

Use with Contact Lenses: XDEMZY contains potassium sorbate, which may discolor soft contact lenses. Contact lenses should be removed prior to instillation of XDEMZY and may be reinserted 15 minutes following its administration.

ADVERSE REACTIONS: The most common adverse reaction with XDEMZY was instillation site stinging and burning which was reported in 10% of patients. Other ocular adverse reactions reported in less than 2% of patients were chalazion/hordeolum and punctate keratitis.

Please [click](#) for full Prescribing Information.

Available by prescription only.

[Date]
[Name of Health Insurance Company]
[Address]
[City, State ZIP]

RE: URGENT - Letter of Medical Necessity for XDEMVI® (lotilaner ophthalmic solution) 0.25%

Patient: [Patient Name]
Group/Policy Number: [Number]
Date of Birth: [Date]

To Whom It May Concern:

I am writing on behalf of my patient, [PATIENT NAME], to document medical necessity and to request coverage of XDEMVI for the treatment of *Demodex* blepharitis, which is an ocular disease caused by a microscopic mite infestation.

Patient Diagnosis and Medical History

[PATIENT NAME] has been in my care since [DATE]. [PATIENT NAME] was diagnosed with *Demodex* blepharitis on the basis of [DIAGNOSTIC FINDINGS, INCLUDING EVIDENCE OF COLLARETTES ON SLIT LAMP EXAM]. As the result of *Demodex* blepharitis, my patient [BRIEF DESCRIPTION OF CLINICAL SIGNS AND SYMPTOMS, THEIR DURATION & SEVERITY, AS WELL AS PREVIOUS EXPERIENCE WITH SYMPTOMATIC THERAPIES AND INTERVENTIONS].

Supporting Evidence

XDEMVI is the only US Food and Drug Administration (FDA)–approved treatment for *Demodex* blepharitis.¹ The efficacy and safety of XDEMVI have been demonstrated in 2 pivotal, randomized, controlled clinical trials that enrolled a total of 833 patients, representing the largest clinical trial program conducted in patients with *Demodex* blepharitis.¹⁻³

Tea tree oil (TTO) is an over-the-counter essential oil that has not been FDA-approved for the treatment of *Demodex* blepharitis.⁴ The mechanism of action is not fully known, and evidence supporting its use in *Demodex* blepharitis is limited, demonstrating only modest improvement while potentially exposing patients to harmful consequences.⁴⁻⁸ A meta-analysis evaluating randomized controlled trials involving 5% to 50% TTO reported a very low certainty of evidence that TTO was helpful in reducing *Demodex* mites in short-term cases (4-6 weeks).⁴ Moreover, terpinen-4-ol, the active ingredient in TTO, has been shown in vitro to be toxic to human meibomian glands at concentrations much lower than those that are used to kill *Demodex* mites.⁹ This suggests that patients may be exposed to toxic levels of terpinen-4-ol when being treated with TTO.

In addition to TTO, another treatment option has also demonstrated limited evidence in treating *Demodex* blepharitis. Ivermectin is an anthelmintic agent that has not been FDA-approved for the treatment of *Demodex* blepharitis.^{10,11} Studies evaluating oral ivermectin are limited by small sample sizes (N≤19) and the absence of a comparator arm, making it difficult to draw conclusions regarding its efficacy in treating *Demodex* blepharitis.^{12,13} Moreover, oral ivermectin may expose patients to unnecessary systemic side effects when treating a predominantly localized disease. Data have shown that microfilaricidal drugs might cause cutaneous and/or systemic reactions of varying severity (the Mazzotti reaction), and neurotoxicity and ophthalmological reactions in patients with onchocerciasis treated with oral ivermectin.¹¹ The limited evidence in treating *Demodex* blepharitis, lack of FDA-approved indication, and significant potential safety concerns should be considered when evaluating treatment options, such as TTO and ivermectin over XDEMVI.

Eye Care Specialist Assessment

I am an eye care specialist in [NAME OF SPECIALTY/BOARD CERTIFICATION AND ANY OTHER PERTINENT QUALIFICATIONS]. My clinical assessment indicates that XDEMZY, the first and only FDA-indicated medication to treat *Demodex* blepharitis, is medically necessary and appropriate for [PATIENT NAME] to directly target and kill *Demodex* mites. Please refer to the Prescribing Information for XDEMZY.

In view of the above information, I believe XDEMZY is medically necessary for this patient with *Demodex* blepharitis. Please note that your formulary currently does not cover a specific treatment for *Demodex* blepharitis, despite the availability of an FDA-approved treatment with XDEMZY. Therefore, I respectfully request that [PAYER NAME] cover XDEMZY for [PATIENT NAME].

Sincerely,

[PHYSICIAN NAME], [DEGREE INITIALS]
[PROVIDER IDENTIFICATION NUMBER]

References:

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