Sample Letter of Appeal for XDEMVY® (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, add any additional information you feel would be important, and refer to the sample on the next page.

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

ADVERSE REACTIONS: The most common adverse reaction with XDEMVY 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.

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

RE: URGENT - Letter of Appeal for XDEMVY® (lotilaner ophthalmic solution) 0.25%
Patient: [Patient Name]
Group/policy number: [Number]
Date of birth: [Date]
Denied prior authorization number: [Number]
Denial date: [Date]

To Whom It May Concern:

I am writing on behalf of my patient, [PATIENT NAME], to request an appeal to reconsider denied coverage of XDEMVY for the treatment of *Demodex* blepharitis, which is an ocular disease caused by a parasitic mite infestation.

As indicated in your letter dated on [DENIAL DATE], XDEMVY coverage was denied due to the following reason:

- [DENIAL REASON STATED IN THE PAYER'S DENIAL LETTER]

Patient Diagnosis and Medical History
[PATIENT NAME] has been in my care since [DATE]. [PATIENT NAME] was diagnosed with *Demodex* blepharitis based on [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 MANAGEMENT AND INTERVENTIONS, INCLUDING OVER-THE-COUNTER TREATMENTS CONTAINING TEA TREE OIL].

Supporting Evidence
XDEMVY is the only FDA-approved prescription treatment for *Demodex* blepharitis.[1] The efficacy and safety of XDEMVY have been demonstrated in two 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]

[IF TEA TREE OIL FAILURE IS REQUIRED PRIOR TO APPROVAL] Tea tree oil (TTO) is an over-the-counter essential oil that is not FDA-approved for the treatment of *Demodex* blepharitis.[4] TTO's 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-analyses 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. The lack of a FDA-approved indication to treat *Demodex* blepharitis, limited evidence in treating *Demodex* blepharitis and potential toxicity to human meibomian glands at sub-therapeutic levels of TTO should be considered when evaluating TTO over XDEMVY for the treatment of *Demodex* blepharitis.

[IF IVERMECTIN FAILURE IS REQUIRED PRIOR TO APPROVAL] Ivermectin is an anthelmintic agent that is not FDA-approved for the treatment of *Demodex* blepharitis.[4,5] Evidence supporting its use in treating *Demodex* blepharitis is limited and treatment may be associated with serious adverse reactions.[4-6] 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.[6,7] 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.[5] The limited evidence in treating *Demodex* blepharitis, lack of FDA-approved indication, and significant safety concerns should be considered when evaluating ivermectin over XDEMVY, an FDA-approved treatment for *Demodex* blepharitis.

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 XDEMVY is warranted, appropriate, and medically necessary for [PATIENT NAME] to directly target and kill *Demodex* mites. Please refer to the Prescribing Information for XDEMVY.

In view of the above information, I believe XDEMVY should be covered for this patient with *Demodex* blepharitis. [IF ORAL IVERMECTIN FAILURE IS REQUIRED PRIOR TO APPROVAL] There is no adequate evidence or sufficient clinical rationale to substantiate off-label use of oral ivermectin for this patient. Therefore, I respectfully request that [PAYER NAME] reconsider coverage of XDEMVY for [PATIENT NAME] since we have an FDA-approved treatment available.

Sincerely,

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

References:

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