Sample Letter of Medical Necessity 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 and refer to the sample on the next page.

Indication and Usage

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.

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

RE: URGENT - Letter of Medical Necessity for XDEMVY® (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 XDEMVY 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 PREVIOUS EXPERIENCE WITH SYMPTOMATIC THERAPIES AND INTERVENTIONS].

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, the first and only FDA-indicated medication to treat *Demodex* blepharitis, is medically necessary and appropriate for [PATIENT NAME] in order to directly target and kill *Demodex* mites. Please refer to the Prescribing Information for XDEMVY.

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

Sincerely,

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