Sample Letter of Medical Necessity for Retreatment With XDEMVY® (lotilaner ophthalmic solution) 0.25%

This sample letter is for informational purposes only. You should modify the content as needed to accurately reflect the specific signs, symptoms, and clinical findings of your patient. 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

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.

To report SUSPECTED ADVERSE REACTIONS, contact Tarsus Pharmaceuticals, Inc. at 1-888-421-4002 or the FDA at 1-800-FDA-1088 (www.fda.gov/medwatch).

Please click for full Prescribing Information.

Available by prescription only.

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[Place your letterhead here]

[Date]
[Medical Director/Appeals Department]
[Name of Health Insurance Company]
[Address]
[City, State ZIP]

RE: URGENT—Letter of Medical Necessity/Request for Coverage of Retreatment With XDEMVY® (lotilaner ophthalmic solution) 0.25%

Patient: [Patient Name]
Date of birth: [MM/DD/YYYY]
Member ID: [ID]
Group/policy number: [Number]
Diagnosis: *Demodex* blepharitis with recurrent, clinically active infestation

To Whom It May Concern:

I am writing on behalf of my patient, [Patient Name], to request coverage for a retreatment course of XDEMVY® (lotilaner ophthalmic solution) 0.25% due to a documented recurrence of *Demodex* blepharitis following an initial course of therapy. [Patient Name] previously completed a full course of XDEMVY and subsequently demonstrated clinical improvement; however, on follow-up examination, objective signs and symptoms of *Demodex* blepharitis have returned, including recurrent collarettes.

XDEMVY is the first and only FDA-approved therapy for *Demodex* blepharitis.[1] Its efficacy and safety were established in 2 pivotal, randomized clinical trials (SATURN-1 and SATURN-2) that enrolled a total of 833 patients, with significant reductions in collarettes and high rates of mite eradication.[1-3]

[Patient Name] has recurrent collarettes confirmed on slit lamp examination. Collarettes are a pathognomonic sign of active *Demodex* mite infestation.[4,5] Sadri et al reported results from a noninterventional safety extension study of the SATURN-1 trial with 1-year follow-up (N=239). Authors noted that return of collarettes in some patients over time is expected, potentially due to reinfestation or survival of a small number of mites, despite initial treatment.[6]

This study demonstrated that while many patients experienced durable benefit, a subset showed recurrence of clinical signs of *Demodex* blepharitis over time. Specifically, the proportion of patients in the study group with 0 to 2 collarettes (grade 0) was 44% at the conclusion of the SATURN-1 study (week 6), 40% at Day 180, and 24% at Day 365.[6] These findings demonstrated that *Demodex* blepharitis may recur in a subset of patients following completion of an initial course of therapy, supporting the medical necessity of retreatment with XDEMVY when objective signs or symptoms return.

Importantly, no new safety concerns were identified during the 1-year follow up.[6]

Given [Patient Name]'s documented recurrence of signs and symptoms, alternative conservative measures may be insufficient and do not treat the underlying mite infestation.[7]

Therefore, I respectfully request approval for retreatment with XDEMVY for this patient.

Sincerely,
[Prescriber Name], [Credentials]
[NPI]
[Practice Name]
[Contact Information]

References:

1. XDEMVY. Prescribing Information. Tarsus Pharmaceuticals, Inc., 2023.
2. Yeu E et al. *Cornea*. 2023;42(4):435-443. doi:10.1097/ICO.0000000000003097
3. Gaddie I et al. *Ophthalmology*. 2023;130(10):1015-1023. doi: 10.1016/j.ophtha.2023.05.030
4. Fromstein SR et al. *Clin Optom (Auckl)*. 2018;10:57-63. doi: 10.2147/OPTO.S142708
5. Trattler W et al. *Clin Ophthalmol*. 2022;16:1153-1164. doi: 10.2147/OPTH.S354692
6. Sadri E et al. *Cornea*. 2024;43(11):1368-1374. doi: 10.1097/ICO.0000000000003484
7. Rhee MK et al. *Eye Contact Lens.* 2023;49(8):311-318. doi: 10.1097/ICL.0000000000001003