Reference number(s)
7566-C

This document applies to the following:

Formulary	Applies
Advanced Control (ACF)	☑
Advanced Control Formulary Chart (ACFC)	☐
Advanced Control – Choice (ACCF)	☐
Basic Control (BC)	☐
Basic Control Chart (BCC)	☐
Standard Control (SF)	☑
Standard Control Formulary Chart (SFC)	☐
Standard Control – Choice (SCCF)	☐
Value (VF)	☐
Value Formulary Chart (VFC)	☐

Formulary	Applies
Managed Medicaid Template (MMT)	☐
Marketplace (MF)	☐
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	☐
Aetna Individual Lives (IVL)	☐
Aetna Fully Insured Advanced Control Formulary (Aetna FI ACF)	☐
Aetna Fully Insured Advanced Control Formulary Chart (Aetna FI ACFC)	☐
Aetna Fully Insured Standard Opt-Out (Aetna FI SOO)	☐

Medical Necessity Criteria
Dry Eye Disease Agents

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Cequa	cyclosporine
Miebo	perfluorohexyloctane
Tryptyr	acoltremon
Xiidra	lifitegrast

Indications

FDA-approved Indications

© 2026 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.

Cequa

Cequa ophthalmic solution is a calcineurin inhibitor immunosuppressant indicated to increase tear production in patients with keratoconjunctivitis sicca (dry eye).

Miebo

Miebo (perfluorohexyloctane ophthalmic solution) is indicated for the treatment of the signs and symptoms of dry eye disease (DED).

Tryptyr

Tryptyr is indicated for the treatment of the signs and symptoms of dry eye disease.

Xiidra

Xiidra (lifitegrast ophthalmic solution) 5% is indicated for the treatment of the signs and symptoms of dry eye disease (DED).

Coverage Criteria

Dry Eye Disease

Authorization may be granted when the requested drug is being prescribed for the treatment of dry eye disease (DED) when ALL of the following criteria are met:

- The patient CANNOT be treated with a formulary alternative (Available Formulary Alternatives: Restasis, Vevye).
- The patient meets ONE of the following:
    - The patient has experienced an inadequate treatment response to a 6-month trial of Restasis AND a 1-month trial of Vevye. [ACTION REQUIRED: Documentation is required for approval.]
    - The patient has experienced an intolerance to, or the patient has a contraindication that would prohibit a trial of Restasis AND Vevye. [ACTION REQUIRED: Documentation is required for approval.]
- The diagnosis of dry eye disease (DED) has been confirmed by slit lamp examination AND a diagnostic test (e.g., Schirmer test, fluorescein dye disappearance test, fluorescein tear break-up time, ocular surface dye staining, tear osmolarity). [ACTION REQUIRED: Documentation is required for approval.]
- The requested drug is being prescribed by, or in consultation with, an ophthalmologist or optometrist.
- The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to aqueous enhancements (e.g., artificial tears, gels, ointments).
- The requested drug will NOT be used in combination with another agent for dry eye disease (e.g., Restasis, Vevye).

© 2026 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.

Continuation of Therapy

Dry Eye Disease

Authorization may be granted when the requested drug is being prescribed for the treatment of dry eye disease (DED) when ALL of the following criteria are met:

- The patient CANNOT be treated with a formulary alternative (Available Formulary Alternatives: Restasis, Vevye).
- The patient meets ONE of the following:
  - The patient has experienced an inadequate treatment response to a 6-month trial of Restasis AND a 1-month trial of Vevye. [ACTION REQUIRED: Documentation is required for approval.]
  - The patient has experienced an intolerance to, or the patient has a contraindication that would prohibit a trial of Restasis AND Vevye. [ACTION REQUIRED: Documentation is required for approval.]
- The patient has achieved or maintained improvement in their signs and symptoms of dry eye disease (DED) from baseline (e.g., ocular irritation, redness, mucous discharge, reduced visual function, ocular surface damage, reduced tear production).
- The positive clinical response to the requested drug from baseline has been confirmed by slit lamp examination AND a diagnostic test (e.g., Schirmer test, fluorescein dye disappearance test, fluorescein tear break-up time, ocular surface dye staining, tear osmolarity). [ACTION REQUIRED: Documentation is required for approval.]
- The requested drug will NOT be used in combination with another agent for dry eye disease (e.g., Restasis, Vevye).

Quantity Limits Apply

Cequa (cyclosporine): 60 single-use vials / 25 days or 180 single-use vials / 75 days

Miebo (perfluorohexyloctane): 1 multi-dose bottle (3 mL) / 25 days or 3 multi-dose bottles (9 mL) / 75 days

Tryptyr (acoltremon): 60 single-dose vials / 25 days or 180 single-dose vials / 75 days

Xiidra (lifitegrast): 60 single-use containers (1 carton) / 25 days or 180 single-use containers (3 cartons) / 75 days

The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

© 2026 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.

Duration of Approval (DOA)

- 7566-C:
  - Miebo (perfluorohexyloctane): Initial therapy DOA: 3 months; Continuation of therapy DOA: 12 months
  - Cequa (cyclosporine), Tryptyr (acoltremon), Xiidra (lifitegrast): Initial Therapy DOA: 4 months; Continuation of therapy DOA: 12 months

References

1. Cequa [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; July 2022.
2. Miebo [package insert]. Bridgewater, NJ: Bausch & Lomb Americas Inc.; October 2025.
3. Restasis [package insert]. North Chicago, IL: AbbVie Inc; September 2024.
4. Restasis Multidose [package insert]. North Chicago, IL: AbbVie Inc; August 2025.
5. Vevye [package insert]. Nashville, TN: Harrow Eye, LLC.; September 2025.
6. Tryptyr [package insert]. Fort Worth, TX: Alcon Laboratories, Inc.; May 2025.
7. Xiidra [package insert]. Bridgewater, NJ: Bausch & Lomb Americas Inc.; December 2023.
8. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2025. https://online.lexi.com. Accessed September 09, 2025.
9. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 09/09/2025).
10. Amescua G, Ahmad S, Cheung AY, et al. Dry Eye Syndrome Preferred Practice Pattern®. Ophthalmology. 2024;131(4):P1-P49.
11. Tauber J, Berdy GJ, Wirta DL, Krösser S, Vittitow JL; GOBI Study Group. NOV03 for Dry Eye Disease Associated with Meibomian Gland Dysfunction: Results of the Randomized Phase 3 GOBI Study. Ophthalmology. 2023;130(5):516-524.
12. Sheppard JD, Kurata F, Epitropoulos AT, Krösser S, Vittitow JL; MOJAVE Study Group. NOV03 for Signs and Symptoms of Dry Eye Disease Associated with Meibomian Gland Dysfunction: The Randomized Phase 3 MOJAVE Study. Am J Ophthalmol. 2023;252:265-274
13. Sheppard JD, Nichols KK. Dry Eye Disease Associated with Meibomian Gland Dysfunction: Focus on Tear Film Characteristics and the Therapeutic Landscape. Ophthalmol Ther. 2023;12(3):1397-1418.
14. Tauber J, Karpecki P, Latkany R, et al. Lifitegrast Ophthalmic Solution 5.0% versus Placebo for Treatment of Dry Eye Disease: Results of the Randomized Phase III OPUS-2 Study. Ophthalmology. 2015;122(12):2423-2431.
15. Holland EJ, Luchs J, Karpecki PM, et al. Lifitegrast for the Treatment of Dry Eye Disease: Results of a Phase III, Randomized, Double-Masked, Placebo-Controlled Trial (OPUS-3). Ophthalmology. 2017;124(1):53-60.

 © 2026 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.

16. Akpek EK, Wirta DL, Downing JE, et al. Efficacy and Safety of a Water-Free Topical Cyclosporine, 0.1%, Solution for the Treatment of Moderate to Severe Dry Eye Disease: The ESSENCE-2 Randomized Clinical Trial. JAMA Ophthalmol. 2023;141(5):459-466.
17. Pattar GR, Wirta D, Jerkins G, et al. Acoltremon Ophthalmic Solution 0.003% for Signs and Symptoms of Dry Eye Disease: Results of Phase 3 Pivotal Studies COMET-2 and COMET-3. Ophthalmology. Published online September 30, 2025.

 © 2026 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.