Reference number(s)
6974-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
Miebo

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
Miebo	perfluorohexyloctane

Indications

FDA-approved Indications

Miebo (perfluorohexyloctane ophthalmic solution) 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 when ALL of the following criteria are met:

- The patient CANNOT be treated with a formulary alternative (Available Formulary Alternatives: Restasis, Xiidra).
- The patient is 18 years of age or older.
- 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 patient meets ONE of the following:
    - The patient has experienced an inadequate treatment response to a 6-month trial of Restasis AND a 3-month trial of Xiidra. [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 Xiidra. [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, Xiidra).

Continuation of Therapy

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

- The patient CANNOT be treated with a formulary alternative (Available Formulary Alternatives: Restasis, Xiidra).
- 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, Xiidra).

Quantity Limits Apply

1 multi-dose bottle (3 mL) / 25 days or 3 multi-dose bottles (9 mL) / 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.

Duration of Approval (DOA)

- 6974-C: Initial therapy DOA: 3 months; Continuation of therapy DOA: 12 months

References

1. Miebo [package insert]. Bridgewater, NJ: Bausch & Lomb Americas Inc.; January 2024.
2. Restasis [package insert]. North Chicago, IL AbbVie Inc; September 2024.
3. Restasis Multidose [package insert]. North Chicago, IL AbbVie Inc; September 2024.
4. Xiidra [package insert]. Bridgewater, NJ: Bausch & Lomb Americas Inc.; December 2023.
5. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2025. https://online.lexi.com. Accessed May 11, 2025.
6. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 05/11/2025).
7. Amescua G, Ahmad S, Cheung AY, et al. Dry Eye Syndrome Preferred Practice Pattern®. Ophthalmology. 2024;131(4):P1-P49.
8. 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.
9. 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
10. 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.

