Oscar Clinical Guideline: Miebo (perfluorohexyloctane) (PG166, Ver. 4)

Miebo (perfluorohexyloctane)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Dry Eye Disease (DED), commonly referred to as dry eye syndrome and also known as keratoconjunctiva sicca (KCS), is a common ocular condition that occurs when the tears are not able to provide adequate lubrication for the eyes. This deficiency manifests through symptoms such as dryness, red eyes, burning and itching eyes, blurred vision, discomfort, and if neglected, more severe visual complications. The underlying causes of DED span a multitude of factors, but predominantly arise from reduced tear production or increased tear evaporation. This can be due to a wide range of causes, such as age, environmental conditions, certain medications (e.g., anticholinergics, antihistamines), or underlying health conditions like Sjogren's disease.

Management of KCS or DED typically includes non-pharmacological management (e.g., frequent blinking, reducing air conditioning/heat, humidifier use), and eye lubricants (e.g., polyethylene glycol or polyvinyl alcohol eye drops and gels). In those with persistent symptoms, providers will typically prescribe topical Restasis (cyclosporine ophthalmic emulsion 0.05%), topical Xiidra (lifitegrast), or other alternative therapies. Other options are punctal plugs to conserve tears, autologous serum tears, and procedures like thermal pulsation.

Miebo (perfluorohexyloctane) is a topical ophthalmic solution used to treat signs and symptoms of dry eye disease. It contains semifluorinated alkanes that help stabilize the tear film and reduce evaporation from the ocular surface. The recommended dosage is one drop instilled in each affected eye four times daily. Miebo works by spreading across the tear film lipid layer to prevent excessive water loss through evaporation. By reducing evaporation, it helps relieve dry eye symptoms like burning, stinging, blurry vision, and discomfort.

Definitions

"Aqueous tear deficiency" refers to reduced production of the aqueous (water) component of tears, leading to dry eye disease.

"Dry Eye Disease (DED)/Dry Eye Syndrome" is an ocular condition wherein tears fail to adequately lubricate the eyes, leading to symptoms like blurred vision and discomfort.

"Documentation" refers to written information, including but not limited to:

- Up-to-date chart notes, relevant test results, and/or relevant imaging reports to support diagnoses; or
- Prescription claims records, and/or prescription receipts to support prior trials of formulary alternatives.

"Keratitis sicca" is another term for keratoconjunctivitis sicca.

"Keratoconjunctivitis sicca"is a condition marked by dryness of the conjunctiva (the membrane lining the eyelids and covering the white part of the eye) and the cornea (the clear, front surface of the eye).

"Ocular burning" is a sensation of burning or stinging in the eyes, potentially caused by certain medications or eye conditions.

"Punctal plugs" are small devices inserted into the tear drainage ducts to conserve tears and treat dry eye disease.

"Schirmer's Test" is a standardized test to measure tear production.
"Sjögren's syndrome" is a chronic autoimmune disorder characterized by dryness of the eyes, mouth, and other mucous membranes due to the body's immune system mistakenly attacking its own cells and tissues.

"Tear Break-Up Time Test" is a diagnostic method that measures the time interval before dry patches form on the eye after a blink, providing insights into tear film stability.

"Tear Evaporation" is the natural process of tears evaporating from the eye surface. An increased rate can result in DED.

"Tear Film" is a thin layer of tears that covers the eye, ensuring lubrication, reducing the risk of infections, and keeping the eye smooth for clear vision.

"Tear Production" is the process of producing fluids to keep the eyes moist, which can be diminished in some individuals leading to DED.

"Thermal pulsation" is a procedure that applies heat and pressure to the eyelids to help treat dry eye associated with meibomian gland dysfunction.

"Xerophthalmia" is a dry eye syndrome caused by a deficiency in vitamin A. It can lead to blindness if not managed.

"[s]" indicates state mandates may apply.

Clinical Indications

Medical Necessity Criteria for Clinical Review

General Medical Necessity Criteria

The Plan considers Miebo (perfluorohexyloctane) medically necessary when ALL of the following criteria are met:

1. The member is 18 years of age or older; *AND*

2. Miebo (perfluorohexyloctane) is being prescribed at a dose and frequency that is within FDA approved labeling OR is supported by compendia or evidence-based published dosing guidelines for the requested indication*; AND*

   The requested medication is being used within the Plan's Quantity Limit of: 3 mL every 30 days.
3. The member meets the applicable Medical Necessity Criteria for Initial Clinical Review or Subsequent Clinical Review listed below.

Medical Necessity Criteria for Initial Clinical Review

Initial Indication-Specific Criteria

Dry Eye Disease

The Plan considers Miebo (perfluorohexyloctane) medically necessary when ALL of the following criteria are met:

4. The member meets the above General Medical Necessity Criteria; *AND*
5. The member meets ONE (1) of the following documented diagnoses:
   a. Dry eye disease, such as:
      i. Chronic dry eye disease*; or*
      ii. Keratitis sicca*; or*
      iii. Keratoconjunctivitis sicca*; or*
      iv. Xerophthalmia*; or*
      v. Any other form of dry eye syndrome*; or*
   b. Dry eye conditions due to systemic inflammatory diseases, such as:
      i. Sjögren's Syndrome*; or*
      ii. Other systemic inflammatory diseases resulting in dry eye conditions (e.g., autoimmune thyroid disease, rheumatoid arthritis)*; or*
   c. Dry eye conditions due to ocular surface diseases, such as:
      i. Ocular Graft vs. Host Disease*; or*
      ii. Corneal Transplant Rejection*; or*
      iii. Other ocular surface diseases resulting in dry eye conditions (e.g., blepharitis, conjunctivitis, herpes simplex keratitis, meibomian gland dysfunction, ocular rosacea).

If the above prior authorization criteria are met, the requested product will be approved for up to 12 months.[s]

Continued Care

Medical Necessity Criteria for Subsequent Clinical Review

Subsequent Indication-Specific Criteria

Dry Eye Disease

The Plan considers Miebo (perfluorohexyloctane) medically necessary when ALL of the following criteria are met:

1. The member meets the above applicable General Medical Necessity Criteria and/or Initial Clinical Review; *AND*
2. Chart documentation indicates EITHER of the following:
    a. The member has shown a clinical improvement[ⁿ] in symptoms since starting the requested medication; *or*
    b. The member has experienced disease stability[ⁿ] since starting the requested medication.

    [ⁿ]*Note: Clinical improvement may be characterized by reduction in signs and symptoms such as ocular discomfort, burning, or dryness, and/or an increase in tear production as measured by standardized tests such as Schirmer's test or tear break-up time. Disease stability refers to a halt in disease progression, with signs and symptoms remaining consistent and not worsening over time. These should be supported by the medical documentation.*

If the above reauthorization criteria are met, the requested product will be approved for up to 12 months.[s]

Experimental / Investigational, unproven[s]

Miebo (perfluorohexyloctane) for any other use is considered experimental, investigational, or unproven. Additionally, the safety and efficacy of Miebo (perfluorohexyloctane) has not been established in patients below the age of 18 years.

References

1. Aggarwal S, Galor A. What's new in dry eye disease diagnosis? Current advances and challenges. F1000Res. 2018;7. Epub December 18, 2018. Available at: https://doi.org/10.12688/f1000research.16468.1.
2. American Academy of Ophthalmology: Dry Eye Syndrome PPP - 2018. American Academy of Ophthalmology. Published November 2018. Available at: https://www.aao.org/preferred-practice-pattern/dry-eye-syndrome-ppp-2018
3. Amescua G, Ahmad S, Cheung AY, Choi DS, Jhanji V, Lin A, Mian SI, Rhee MK, Viriya ET, Mah FS, Varu DM; American Academy of Ophthalmology Preferred Practice Pattern Cornea/External Disease Panel. Dry Eye Syndrome Preferred Practice Pattern®. Ophthalmology. 2024 Apr;131(4):P1-P49. doi: 10.1016/j.ophtha.2023.12.041. Epub 2024 Feb 12. PMID: 38349301.
4. Dogru M, Tsubota K. Pharmacotherapy of dry eye. Expert Opin Pharmacother. 2011;12(3):325-334.
5. Foulks GN, Forstot SL, Donshik PC, et al. Clinical guidelines for management of dry eye associated with sjogren disease. Ocul Surf. 2015;13(2):118-132.
6. Goldstein MH et al: Dry eye disease. Ophthalmology. 5th ed. Elsevier; 2019:276-81.e2

7. McCann P, Abraham AG, Mukhopadhyay A, et al. Prevalence and Incidence of Dry Eye and Meibomian Gland Dysfunction in the United States: A Systematic Review and Meta-analysis. JAMA Ophthalmol. 2022 Dec 1;140(12):1181-1192. doi: 10.1001/jamaophthalmol.2022.4394.
8. Miebo (perfluorohexyloctane) [prescribing information]. Bridgewater, NJ: Bausch & Lomb Americas Inc; October 2025.
9. Milner MS et al: Dysfunctional tear syndrome: dry eye disease and associated tear film disorders - new strategies for diagnosis and treatment. Curr Opin Ophthalmol. 27 Suppl 1:3-47, 2017
10. Protzko EE, Segal BA, Korenfeld MS, Krösser S, Vittitow JL. Long-Term Safety and Efficacy of Perfluorohexyloctane Ophthalmic Solution for the Treatment of Patients With Dry Eye Disease: The KALAHARI Study. Cornea. 2024 Sep 1;43(9):1100-1107. doi: 10.1097/ICO.0000000000003418. Epub 2023 Nov 3.
11. Pucker AD, Ng SM, Nichols JJ. Over the counter (OTC) artificial tear drops for dry eye syndrome. Cochrane Database of Systematic Reviews 2016, Issue 2. Art. No.: CD009729. DOI: 10.1002/14651858.CD009729.pub2.
12. Schmidl D, Bata AM, Szegedi S, et al. Influence of Perfluorohexyloctane Eye Drops on Tear Film Thickness in Patients with Mild to Moderate Dry Eye Disease: A Randomized Controlled Clinical Trial. J Ocul Pharmacol Ther. 2020 Apr;36(3):154-161. doi: 10.1089/jop.2019.0092. Epub 2020 Jan 2.
13. 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 Aug;252:265-274. doi: 10.1016/j.ajo.2023.03.008. Epub 2023 Mar 21. PMID: 36948372.
14. Steven P, Augustin AJ, Geerling G, et al. Semifluorinated Alkane Eye Drops for Treatment of Dry Eye Disease Due to Meibomian Gland Disease. J Ocul Pharmacol Ther. 2017 Nov;33(9):678-685. doi: 10.1089/jop.2017.0042. Epub 2017 Sep 18.
15. 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 May;130(5):516-524. doi: 10.1016/j.ophtha.2022.12.021. Epub 2022 Dec 24.
16. Tauber J, Wirta DL, Sall K, et al. A Randomized Clinical Study (SEECASE) to Assess Efficacy, Safety, and Tolerability of NOV03 for Treatment of Dry Eye Disease. Cornea. 2021 Sep 1;40(9):1132-1140. doi: 10.1097/ICO.0000000000002622.

Clinical Guideline Revision / History Information

Original Date: 9/21/2023

Reviewed/Revised: 10/29/2024, 01/01/2026, 12/01/2026