MEDICAL MUTUAL®

Drug Policy

Policy:	Miebo (perfluorohexyloctane ophthalmic solution)	Annual Review Date: 04/18/2024 Last Revised Date: 04/18/2024

OVERVIEW

Miebo, a semifluorinated alkane, is indicated for the treatment of the signs and symptoms of **dry eye disease** (DED).[1] The safety and effectiveness of Miebo in pediatric patients < 18 years of age have not been established.

There are no data to support concomitant use of Miebo with other ophthalmic medications for DED (e.g., cyclosporine [Cequa™, Restasis®, Vevye™), Tyrvaya® (varencilcine nasal solution), Xiidra® (lifitegrast ophthalmic solution).

Guidelines

The American Academy of Ophthalmology (AAO) published a Preferred Practice Pattern for the treatment of dry eye syndrome (used interchangeably with DED) in 2018.[2] The AAO classifies dry eye as mild, moderate, or severe, based on signs and symptoms of the disease. Treatment recommendations for DED are listed in a four-step progression but specific therapies may be chosen from any category, regardless of the level of disease severity, depending on provider experience and patient preference.

POLICY STATEMENT

This policy involves the use of Miebo. Prior authorization is recommended for pharmacy benefit coverage of Miebo. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Miebo as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Miebo be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Miebo is recommended in those who meet the following criteria:

1. **Dry Eye Disease, Initial Use.**
   Criteria. *Patient must meet the following criteria*
   A. The patient is 18 years of age or older; AND

B. The medication is prescribed by or in consultation with an ophthalmologist, optometrist, or rheumatologist; AND
C. The provider has administered testing for one of the following homeostasis markers with corresponding results (a, b, c, or d):
    a. Schirmer's test (< 5 mm of wetting over 5 minutes), OR
    b. Non-invasive tear breakup time (< 10 s), OR
    c. Osmolarity (≥ 308 mOsm/L in either eye or interocular difference of > 8 mOsm/L), OR
    d. Ocular surface staining (> 5 corneal spots, > 9 conjucntival spots, or lid margin [≥ 2 mm length and ≥ 25% width]); AND
D. If the diagnosis is mild dry eye disease, the patient has tried and failed on preservative free artificial tears.

2. Dry Eye Disease, Continuation of Therapy.
Criteria. *Patient must meet the following criteria*

A. The patient is 18 years of age or older; AND
B. The medication is prescribed by or in consultation with an ophthalmologist, optometrist, or rheumatologist; AND
C. The patient has had a beneficial response to therapy, including reduced eye irritation, dryness, red eyes, or burning).

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Miebo has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. **Concomitant use with an ophthalmic cyclosporine product (Cequa, Restasis, Vevye), Tyrvaya (varenicline nasal solution), or Xiidra (lifitegrast ophthalmic solution).** There are no data to support the concomitant use of Miebo with Cequa/Restasis/Vevye, Tyrvaya, or Xiidra.

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational, or experimental, not within the scope of benefits afforded to the member and/or a

pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Miebo™ ophthalmic solution [prescribing information]. Bridgewater, NJ: Bausch & Lomb; May 2023.
2. Akpek E, Amescua G, Farid M, et al. American Academy of Ophthalmology Preferred Practice Pattern Cornea and External Disease Panel. Dry Eye Syndrome Preferred Practice Pattern®. *Ophthalmology*. 2019 Jan;126(1):286-334.