



Federal Employee Program.  
Blue Cross Blue Shield Association  
750 9th St NW, Suite 900  
Washington, D.C. 20001  
1-800-624-5060  
Fax 1-877-378-4727

## 5.90.069

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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	January 1, 2026
<b>Subsection:</b>	Topical Products	<b>Original Policy Date:</b>	December 29, 2023
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**Last Review Date:** March 7, 2025

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### Miebo

#### Description

Miebo (perfluorohexyloctane ophthalmic solution)

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#### Background

Miebo (perfluorohexyloctane) ophthalmic solution is a semifluorinated alkane used to treat signs and symptoms of dry eye disease. Miebo is sterile, preservative-free, water-free, and steroid-free and packaged without excipients as active-ingredient only. Dry eye disease includes a group of conditions in which the eye does not produce an adequate volume of tears or when the tears are not of the correct consistency. In patients whose tear evaporation is excessive due to an altered tear liquid layer, Miebo forms a monolayer at the air-liquid interface of the tear film and reduces evaporation. The exact mechanism of action is unknown (1-2).

#### Regulatory Status

FDA-approved indication: Miebo is a semifluorinated alkane indicated for treatment of the signs and symptoms of dry eye disease (DED) (1).

Each multidose bottle contains 3 mL of Miebo. The Miebo drop is small (11  $\mu$ L), with each bottle containing approximately 270 drops, providing a 1 month supply (3).

The safety and effectiveness of Miebo in pediatric patients less than 18 years of age have not been established (1).

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#### Related policies

Cyclosporine Ophthalmics, Eysuvis, Tyrvaya, Xiidra

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## Policy

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Miebo may be considered **medically necessary** if the conditions indicated below are met.

Miebo may be considered **investigational** for all other indications.

## Prior-Approval Requirements

**Age** 18 years of age or older

### Diagnosis

Patient must have the following:

1. Dry Eye Disease
  - a. **NO** dual therapy with another legend ophthalmic for the treatment of dry eyes (see Appendix 1)

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## Prior – Approval Renewal Requirements

**Age** 18 years of age or older

### Diagnosis

Patient must have the following:

1. Dry Eye Disease
  - a. Patient has had an improvement in symptoms
  - b. **NO** dual therapy with another legend ophthalmic for the treatment of dry eyes (see Appendix 1)

## Policy Guidelines

### Pre - PA Allowance

None

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## Prior - Approval Limits

**Quantity** 3 bottles (9ml) every 90 days

**Duration** 12 months

## Prior – Approval Renewal Limits

Same as above

### Rationale

#### Summary

Miebo (perfluorohexyloctane) ophthalmic solution is used to treat the signs and symptoms of dry eye disease (DED). It contains 100% of active ingredient, and free from water, preservative, and steroid. Dry eye disease includes a group of conditions in which the eye does not produce an adequate volume of tears or when the tears are not of the correct consistency. In patients whose tear production is presumed to be suppressed due to ocular inflammation due to dry eye disease, Miebo forms a monolayer at the air-liquid interface of the tear film and reduce evaporation. The exact mechanism of action is unknown. Patient should be advised that contact lenses should be removed prior to and for at least 30 minutes after administration of Miebo. The safety and effectiveness of Miebo in pediatric patients less than 18 years of age have not been established (1-2).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Miebo while maintaining optimal therapeutic outcomes.

#### References

1. Miebo [package insert]. Bridgewater, NJ: Bausch & Lomb Americas Inc.; May 2023.
2. Dry Eyes Syndrome Preferred Practice Pattern. American Academy of Ophthalmology. September 2018.
3. The MIEBO experience. Accessed from: <https://www.miebo-ecp.com/the-miebo-experience/>.

### Policy History

Date	Action
December 2023	Addition to PA
March 2024	Annual review
July 2024	Per FEP, added TBUT requirement for initiation and changed quantity limit to 3 bottles per 90 days

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September 2024      Annual review  
March 2025      Annual review  
January 2026      Per trade, removed prescriber, try and fail requirements, tear break up time, and determination of meibomian gland dysfunction and also changed diagnosis to signs and symptoms of dry eye disease

## Keywords

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**This policy was effective with interim approval on January 1, 2026 and will be reviewed by the FEP® Pharmacy and Medical Policy Committee on March 6, 2026.**

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## Appendix 1 - List of Legend Ophthalmic Medications for Dry Eye

Generic Name	Brand Name
cyclosporine	Cequa
cyclosporine	Restasis
cyclosporine	Vevye
lifitegrast	Xiidra
loteprednol	Eysuvis
perfluorohexyloctane	Miebo
varenicline	Tyrvaya

\*Verkazia is not approved for dry eye