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Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Topical Products	**Original Policy Date:**	December 29, 2023
Subject:	Miebo	**Page:**	1 of 5

Last Review Date: March 8, 2024

Miebo

Description

Miebo (perfluorohexyloctane ophthalmic solution)

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-ingedient 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).

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

Related policies
Cyclosporine Ophthalmics, Eysuvis, Tyrvaya, Xiidra

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. Chronic dry eye
    a. Patient has been evaluated by an optometrist, ophthalmologist, or a physician specializing in the treatment of the patient's condition
    b. Prescriber has determined that patient's condition is likely due to meibomian gland dysfunction
    c. Inadequate treatment response, intolerance, or contraindication to **ONE** product from **EACH** of the following categories of dry eye treatment:
        i. Cellulose or polyol containing artificial tears (e.g., active ingredients such as: hydroxyethyl cellulose, methylcellulose, Dextran 70, Glycerin, povidone, etc.)
        ii. Lipid-containing artificial tears (e.g., active ingredients such as: mineral oil, castor oil, flaxseed oil, etc.)
        iii. Legend ophthalmic for the treatment of dry eyes (see Appendix 1)
    d. **NO** dual therapy with another legend ophthalmic for the treatment of dry eyes (see Appendix 1)

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Chronic dry eye
    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

Prior - Approval Limits

Quantity 12 bottles (36ml) every 90 days

Duration 12 months

Prior – Approval *Renewal* Limits
Same as above

Rationale

Summary

Miebo (perfluorohexyloctane) ophthalmic solution is used to treat 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.

Policy History

Date	Action
December 2023	Addition to PA
March 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.

Appendix 1 - List of Legend Ophthalmic Medications for Dry Eye

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