Effective Date **12/15/2023**
Next Review Date… **12/1/2024**
Coverage Policy Number **IP0583**

Perfluorohexyloctane Ophthalmic Solution

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Related Coverage Resources

Quantity Limitations

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for perfluorohexyloctane ophthalmic solution (**Miebo**™).

Additional criteria that support the review for medical necessity exceptions of non-covered products are located in the Non-Covered Product Table by the respective plan type and drug list where applicable.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Perfluorohexyloctane ophthalmic solution (Miebo) is considered medically necessary when the following are met:

Dry Eye Disease. Individual meets **ALL** of the following criteria:
A. Age 18 years or older
B. Non-Covered Product Criteria is met, refer to below table(s)

Employer Group Non-Covered Products and Criteria:

Non-Covered Product	Criteria
Miebo (perfluorohexyloctane ophthalmic solution)	Documentation of failure, contraindication, or intolerance to **BOTH** of the following: 1. **ONE** of the following: A. cyclosporine 0.05% ophthalmic emulsion B. Cequa (cyclosporine 0.09% ophthalmic solution) 2. Xiidra (lifitegrast 5% ophthalmic solution)

Individual and Family Plan Non-Covered Products and Criteria:

Non-Covered Product	Criteria
Miebo (perfluorohexyloctane ophthalmic solution)	Documentation of failure, contraindication, or intolerance to cyclosporine 0.05% ophthalmic emulsion

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When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Continuation of perfluorohexyloctane ophthalmic solution (Miebo) is considered medically necessary for Dry Eye Disease when the above medical necessity criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration: up to 12 months
Reauthorization approval duration: up to 12 months

Conditions Not Covered

Any other use is considered experimental, investigational or unproven, including the following (this list may not be all inclusive):

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.

Background

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.

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.