Drug Coverage Policy

Effective Date.....08/15/2024
Coverage Policy Number..... IP0583
Policy Title.....Miebo

Ophthalmology – Dry Eye Disease – Miebo For Individual and Family Plans

- Miebo™ (perfluorohexyloctane ophthalmic solution - Bausch & Lomb)

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. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment and have discretion in making individual coverage determinations. 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.

Cigna Healthcare Coverage Policy

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.

Guidelines
The American Academy of Ophthalmology (AAO) Dry Eye Syndrome Preferred Practice Pattern® (2024) notes dry eye syndrome is also known as dry eye disease or keratoconjunctivitis sicca.[2] Dry eye is generally classified according to both symptoms and signs (i.e., mild, moderate, or

severe); however, there is an emphasis on symptoms over signs. Management of dry eye is listed as a four-step staged approach, but specific therapies may be chosen from any step, regardless of the level of disease severity, depending on provider experience and patient preference. Miebo, as well as other FDA-approved therapies for dry eye disease (cyclosporine ophthalmic products, Tyrvaya® [varenicline nasal spray], and Xiidra® [lifitegrast ophthalmic solution]), are noted as Step 2 options in the Preferred Practice Pattern. The AAO notes use of any of these FDA-approved products may lead to improvement of patient symptoms and/or signs but none has been proven more effective than the other in head-to-head trials; there are no direct comparisons in a prospective clinical trial in the literature.

Medical Necessity Criteria

Miebo is considered medically necessary when the following is met:

FDA-Approved Indication

1. **Dry Eye Disease.** Approve for 1 year if the patient meets both of the following (A and B):
   A. Patient is ≥ 18 years of age.
   B. Preferred product criteria is met for the product(s) as listed in the below table(s)
   Note: Examples of dry eye disease include dry eye syndrome and keratoconjunctivitis sicca

Individual and Family Plans:

Product	Criteria
Miebo (perfluorohexyloctane ophthalmic solution)	ONE of the following: 1. The patient has tried, and according to the prescriber, has experienced inadequate efficacy OR significant intolerance with cyclosporine ophthalmic 0.05% emulsion 2. The patient has diagnosed Meibomian gland disease

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.

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

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven (criteria will be updated as new published data are available).

References

1. Miebo™ ophthalmic solution [prescribing information]. Bridgewater, NJ: Bausch & Lomb; May 2023.
2. Amescua G, Ahmad S, Cheung AY, et al. American Academy of Ophthalmology Preferred Practice Pattern Cornea and External Disease Panel. Dry Eye Syndrome Preferred Practice Pattern®. *Ophthalmology*. 2024;131(4);P1-P49.

Revision Details

Type of Revision	Summary of Changes	Date
Selected Revision	**Dry Eye Disease:** Keratoconjunctivitis sicca was added to the Note of examples of dry eye disease. **Updated preferred product criteria** by adding an exception for patients with Meibomian gland disease.	8/01/2024

The policy effective date is in force until updated or retired.