Clinical Policy: Perfluorohexyloctane (Miebo)

Reference Number: CP.PMN.290
Effective Date: 09.01.23
Last Review Date: 08.24
Line of Business: Commercial, HIM, Medicaid Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Perfluorohexyloctane (Miebo™) is a semifluorinated alkane topical ophthalmic solution.

FDA Approved Indication(s)

Miebo is indicated for the treatment of the signs and symptoms of dry eye disease (DED).

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Miebo is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Dry Eye Disease (must meet all)**:**

1. Diagnosis of DED associated with meibomian gland dysfunction (MGD);
2. Age ≥ 18 years;
3. Failure of an artificial tears agent (*see Appendix B for examples*) at up to maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated;
4. Failure of at least one ophthalmic anti-inflammatory agent (*see Appendix B for examples*) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
5. Failure of generic ophthalmic cyclosporine emulsion 0.05% (generic Restasis®), unless contraindicated or clinically significant adverse effects are experienced;
6. Dose does not exceed both of the following (a and b):
   a. 4 drops per day in each affected eye;
   b. 4 bottles per 30 days.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business:

CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or

b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Dry Eye Disease (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B)*;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 4 bottles per 30 days.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 2 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies –

CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
DED: dry eye disease
MGD: meibomian gland dysfunction

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
OTC artificial tear product examples include but are not limited to: • Glycerin, hypromellose, polyethylene glycol ophthalmic solution (Visine®) • artificial tear ophthalmic ointment (Refresh P.M.®) • white petrolatum-mineral oil ophthalmic ointment (Systane® Nighttime) • carboxymethylcellulose ophthalmic solution (Refresh® Tears) • polyvinyl alcohol ophthalmic solution 1.4%	Solution/gel: 1-2 drops into the affected eye(s) 2-4 times/day as needed Ointment: Apply small amount (~1/4 inch) to the inside of the lower eyelid 1-4 times/day as needed	Varies
Ophthalmic anti-inflammatory agents: • loteprednol suspension/gel (Lotemax®) • Maxidex® (dexamethasone solution/suspension) • fluorometholone ointment/suspension (FML®, FML Forte®) • prednisolone (Pred Forte®, Pred Mild®) Note: Ophthalmic NSAIDs are not indicated for DED.	Varies	Varies
cyclosporine (Restasis)	1 drop OU BID	2 drops/eye/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings
None reported

Appendix D: General Information
- Per American Academy of Ophthalmology (AAO) guidelines, artificial tears are the standard therapy for all severity of dry eyes.

- If artificial tears are inadequate, then the next trial in therapy per AAO guidelines would be ophthalmic anti-inflammatory therapies such as topical non-glucocorticoid immunomodulatory drugs (e.g., cyclosporine), topical LFA-1 antagonist drugs (e.g., lifitegrast), and topical corticosteroid drugs (e.g., loteprednol, prednisolone).

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
DED	Instill one drop into affected eye(s) four times daily	4 drops/eye/day

VI. Product Availability

Ophthalmic solution: 3 mL multiple-dose bottle containing 100% perfluorohexyloctane

VII. References

1. Miebo Prescribing Information. Bridgewater, NJ: Bausch & Lomb Americas Inc.; May 2023. Available at: www.accessdata.fda.gov/drugsatfda_docs/label/2023/216675s000lbl.pdf. Accessed May 24, 2024.
2. American Academy of Ophthalmology Cornea/External Disease Committee. Preferred Practice Pattern® Guidelines. Dry Eye Syndrome. San Francisco, CA. American Academy of Ophthalmology; October 2023. Available at: www.aao.org/ppp. Accessed May 24, 2024.
3. Tauber J, Berdy GJ, Wirta DL, et al. NOV03 for dry eye disease associated with meibomian gland dysfunction: results of the randomized phase 3 GOBI study. *Ophthalmology*. 2023;130(5):516-524.
4. Sheppard JD, Kurata F, Epitropoulos AT, et al. NOV03 for signs and symptoms of dry eye disease associated with meibomian gland dysfunction: the randomized phase 3 MOJAVE study. *Am J Ophthalmol*. 2023;S0002-9394(23)00098-3.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	05.24.23	08.23
3Q 2024 annual review: no significant changes; clarified "non-prescription wetting agents" to artificial tears; revised Appendix B to list commercially available example products and added note that ophthalmic NSAIDs are not indicated for DED; references reviewed and updated.	05.28.24	08.24

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health

plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.