Oscar Clinical Guideline: Miebo (perfluorohexyloctane) (PG166, Ver. 1)

Miebo (perfluorohexyloctane)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Dry Eye Disease (DED), commonly referred to as dry eye syndrome, is a common ocular condition that occurs when the tears are not able to provide adequate lubrication for the eyes. This deficiency manifests through symptoms such as blurred vision, discomfort, and if neglected, more severe visual complications. The underlying causes of DED span a multitude of factors, but predominantly arise from reduced tear production or increased tear evaporation. This can be due to a wide range of causes, such as age, environmental conditions, certain medications, or underlying health conditions like Sjogren's disease.

Diagnosis of dry eye disease typically involves assessing different aspects of the tear film to provide insights into its stability. One common method is the tear break-up time test, which measures the time it takes for dry spots to appear on the eye after a blink. Other methods may also be used depending on the specific circumstances and symptoms of the patient.

Treatment options are varied and often depend on the underlying cause of the condition.

- For many patients, symptoms may be improved or relieved by simply making lifestyle changes, such as reducing screen time or using humidifiers to increase moisture in the environment.
- Over-the-counter eye drops, gels, and ointments that aim to replace or supplement the natural tear film can provide temporary relief for mild to moderate symptoms.
- Prescription medications may also be used, particularly for more severe cases or when the condition is due to an underlying health issue.
- In some cases, procedures may be used to help manage dry eye disease. For example, special contact lenses designed to help retain moisture on the eye surface can be used, or surgical procedures may be performed to block the tear ducts and thus reduce tear loss.

Miebo (perfluorohexyloctane) is a topical ophthalmic solution used to treat signs and symptoms of dry eye disease. It contains semifluorinated alkanes that help stabilize the tear film and reduce evaporation from the ocular surface. The recommended dosage is one drop instilled in each affected eye four times daily. Miebo works by spreading across the tear film lipid layer to prevent excessive water loss through evaporation. By reducing evaporation, it helps relieve dry eye symptoms like burning, stinging, blurry vision, and discomfort.

Definitions

"**Dry Eye Disease (DED)/Dry Eye Syndrome**" is an ocular condition wherein tears fail to adequately lubricate the eyes, leading to symptoms like blurred vision and discomfort.

"**Schirmer's Test**" is a standardized test to measure tear production.

"**Tear Break-Up Time Test**" is a diagnostic method that measures the time interval before dry patches form on the eye after a blink, providing insights into tear film stability.

"**Tear Evaporation**" is the natural process of tears evaporating from the eye surface. An increased rate can result in DED.

"**Tear Film**" is a thin layer of tears that covers the eye, ensuring lubrication, reducing the risk of infections, and keeping the eye smooth for clear vision.

"**Tear Production**" is the process of producing fluids to keep the eyes moist, which can be diminished in some individuals leading to DED.

Medical Necessity Criteria for Initial Authorization

The Plan considers **Miebo (perfluorohexyloctane)** medically necessary when **ALL** of the following criteria are met:

1. The medication is being prescribed by or in consultation with an eye care specialist (ophthalmologist or optometrist); ***AND***
2. The member is 18 years of age or older; ***AND***
3. The member has a diagnosis of chronic dry eye disease; ***AND***
4. The member is unable to use, or has adequately tried and failed **TWO** different over-the-counter (OTC) eye lubricants/artificial tears (eye drops, gel, or ointment) used daily for at least 30 days each; ***AND***
5. The prescribing provider has submitted required clinical documentation (e.g., chart notes, names of the OTC products and/or medications that the member has tried and failed, previous treatment outcomes, etc.) for review.

If the above prior authorization criteria are met, Miebo (perfluorohexyloctane) will be approved for 12 months.

Medical Necessity Criteria for Reauthorization

Reauthorization for 12 months will be granted if **BOTH** of the following are met:

1. the member continues to meet the applicable initial criteria***; AND***
2. chart documentation indicates **EITHER** of the following:
    a. The member has shown a clinical improvement⇅ in symptoms since starting the requested medication; ***or***
    b. The member has experienced disease stability⇅ since starting the requested medication.

⇅*Note: Clinical improvement may be characterized by reduction in signs and symptoms such as ocular discomfort, burning, or dryness, and/or an increase in tear production as measured by standardized tests such as Schirmer's test or tear break-up time. Disease stability refers to a halt in disease progression, with signs and symptoms remaining consistent and not worsening over time. These should be supported by the medical documentation.*

Experimental or Investigational / Not Medically Necessary

Miebo (perfluorohexyloctane) for any other indication or use is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven. Additionally, the safety and efficacy of Miebo (perfluorohexyloctane) has not been established in patients below the age of 18 years.

References

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8. Milner MS et al: Dysfunctional tear syndrome: dry eye disease and associated tear film disorders - new strategies for diagnosis and treatment. Curr Opin Ophthalmol. 27 Suppl 1:3-47, 2017

Clinical Guideline Revision / History Information

Original Date: 9/21/2023 Reviewed/Revised: