

Policy Name:	Dry Eye Disease Step Edit	Policy#:	3203P
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Purpose of the Policy

The purpose of this policy is to define the electronic step-edit criteria for coverage of specific products used for the treatment of dry eye disease including Tyrvaya (varenicline) and Miebo (perfluoroheptyloctane).

Statement of the Policy

Health Alliance Medical Plans will approve the use of Tyrvaya (varenicline) or Miebo (perfluoroheptyloctane) under the pharmacy benefit when the following step-edit criteria have been met.

Criteria

1. Step-Edit Criteria

- 1.1 An electronic step-edit is in place that requires a previous paid claim for Xiidra AND cyclosporine ophthalmic emulsion or Restasis
- 1.2 Provider can submit medical chart documentation of previous trial and subsequent failure of two previous therapies or contraindication to all
- 1.3 For Tyrvaya: step therapy through eye products can be bypassed if patient unable to tolerate eye formulations
- 1.4 For Miebo: step therapy can be bypassed if provider submits clinical documentation of Meibomian gland dysfunction

2. Managed Dose Limit

- 2.1 Tyrvaya: 8.4mL per 30 days
- 2.2 Miebo: 12mL per 30 days

3. Approval Period

- 3.1 12 months

CPT Codes

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HCPCS Codes

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References

- 1. Tyrvaya (varenicline) [prescribing information]. Princeton, NJ: Oyster Point Pharma; October 2021.
- 2. Miebo (perfluoroheptyloctane) [prescribing information]. Bridgewater, NJ: Bausch & Lomb Americas Inc; January 2024.

3. Akpek EK, Amescua G, Farid M, et al (American Academy of Ophthalmology Preferred Practice Pattern Cornea/External Disease Committee). Dry Eye Syndrome Preferred Practice Pattern. *Ophthalmology*. 2024 Feb;131(4):P1-P49.
4. Wirta D, Vollmer P, Paauw J, et al; ONSET-2 Study Group. Efficacy and Safety of OC-01 (Varenicline Solution) Nasal Spray on Signs and Symptoms of Dry Eye Disease: The ONSET-2 Phase 3 Randomized Trial. *Ophthalmology*. 2022 Apr;129(4):379-387.
5. Sheppard JD, Kurata F, Epitropouls 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 Aug;252:265-274.

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DISCLAIMER

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