Clinical Policy: Varenicline (Tyrvaya)

Reference Number: NH.PMN.273
Effective Date: 12.24
Last Review Date: 10.24
Line of Business: Medicaid

Revision Log

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

Description
Varenicline (Tyrvaya®) nasal spray is a cholinergic agonist.

FDA Approved Indication(s)
Tyrvaya 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 Tyrvaya is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

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

1. Diagnosis of DED;
2. Age ≥ 18 years;
3. Failure of artificial tears agent *(see Appendix B for examples)* at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
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. Trial and failure of two (2) preferred products, unless contraindicated or clinically significant adverse effects are experienced;
6. Dose does not exceed 2 nasal spray bottles per 30 days.

Approval duration: 6 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 the following policy CP.PMN.255; or

b. For drugs NOT on the PDL, the non-formulary policy for the relevant line of business: CP.PMN.16; 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.PMN.53.

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 2 nasal spray 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 PDL, the no coverage criteria policy CP.PMN.255; or
   b. For drugs NOT on the PDL, the non-formulary policy CP.PMN.16; 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: CP.PMN.53.

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.PMN.53 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
AAO: American Academy of Ophthalmology
DED: Dry Eye Disease
FDA: Food and Drug Administration

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: • 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 agent: • loteprednol suspension (Lotemax®) • Maxidex® (dexamethasone solution/suspension • fluorometholone ointment/suspension (FML®, FML® Forte®, Flarex®) • prednisolone (Pred Mild®) Note: Ophthalmic NSAIDs are not indicated.	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

- Contraindication(s): None reported
- Boxed warning(s): 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	1 spray (0.03 mg/ actuation) in each nostril twice daily	2 sprays/nostril/day

VI. Product Availability

Nasal spray: 0.03 mg of varenicline in each spray (0.05 mL)

VII. References

1. Tyrvaya Prescribing Information. Princeton, NJ. Oyster Point Pharma, Inc. October 2021. Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/213978s000lbl.pdf. Accessed November 2, 2023.
2. American Academy of Ophthalmology Cornea/External Disease Committee. Preferred Practice Pattern® Guidelines. Dry Eye Syndrome. Chicago, IL: American Academy of Ophthalmology; November 2018. Available at: www.aao.org/ppp. Accessed November 2, 2023.
3. Aragona P, Giannaccare G, Mencucci R, et al. Modern approach to the treatment of dry eye, a complex multifactorial disease: a P.I.C.A.S.S.O. board review. British Journal of Ophthalmology 2021;105:446-453. http://dx.doi.org/10.1136/bjophthalmol-2019-315747.
4. Clinical Pharmacology [database online]. Tampa, FL: Elsevier; 2023. URL: www.clinicalkeys.com/pharmacology.
5. Wirta D, Torkildsen GL, Boehmer B, et al. ONSET-1 Phase 2b randomized trial to evaluate the safety and efficacy of OC-01 (varenicline solution) nasal spray on signs and symptoms of dry eye disease. Cornea. 2022 Oct 1;41(10):1207-1216. doi: 10.1097/ICO.0000000000002941.
6. 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. doi: 10.1016/j.ophtha.2021.11.004.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	10.24	12.24

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.