Clinical Policy: Varenicline (Tyrvaya)

Reference Number: ERX.NPA.164
Effective Date: 03.01.22
Last Review Date: 02.22
Line of Business: Commercial, 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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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 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 clinically significant adverse effects are experienced or all are contraindicated;
5. Failure of Restasis®, unless contraindicated or clinically significant adverse effects are experienced;
6. Failure of Xiidra®, unless contraindicated or clinically significant adverse effects are experienced;
7. Dose does not exceed 2 nasal spray bottles per 30 days.

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
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. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 policy – ERX.PA.01 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 and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Artificial tear Products • Visine® dry eye relief • Refresh P.M.® (*artificial tear ophthalmic ointment)* • Systane® Nighttime (white petrolatum-mineral oil *ophthalmic* ointment) • Nature's Tears® (hypromellose *ophthalmic* solution 0.4%) • Artificial Tears *(polyvinyl alcohol ophthalmic* solution *1.4%)* • Lacri-Lube® *(artificial tears ointment)*	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 (Lotemax®) • Maxidex® (dexamethasone solution/suspension • Fluorometholone ointment/suspension (FML®, FML® Forte®) • prednisolone (Omnipred®, Pred Forte®, Pred Mild®)	Varies	Not applicable
Xiidra® (lifitegrast)	1 drop OU BID	2 drops/eye/day
Restasis® (cyclosporine)	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. liftegrast), and topical corticosteroid drugs (e.g. loteprednol, prednislone).

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 10, 2021.
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 10, 2021.
3. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed November 10, 2021.
4. Clinical and Economic Evidence Dossier for Tyrvaya (varenicline solution) Nasal Spray 0.03 mg. Princeton, NJ. Oyster Point Pharma, Inc. October 2021.
5. ClinicalTrials.gov. NCT03636061 Clinical trial to evaluate the efficacy of OC-01 nasal spray on signs and symptoms of dry eye disease (the ONSET-1 study). August 20218. Available at https://clinicaltrials.gov/ct2/show/study/NCT03636061. Assessed November 10, 2021.
6. ClinicalTrials.gov. NCT04036292 Clinical trial to evaluate the efficacy of OC-01 (varenicline) nasal spray on signs and symptoms of dry eye disease (the ONSET-2 study). July 2019. Available at https://clinicaltrials.gov/ct2/show/study/NCT04036292?term=Oyster+Point&draw=2. Assessed November 10, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	11.23.21	02.22

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.