Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 02/01/2022**
Policy Number: PA.CP.PMN.273	**Effective Date: 01/2022** **Revision Date: 01/2022**
Policy Name: Varenicline (Tyrvaya)	

Type of Submission – Check all that apply:

- ✓ **New Policy**
- ☐ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

Name of Authorized Individual (Please type or print): **Venkateswara R. Davuluri, MD**	**Signature of Authorized Individual:**

Clinical Policy: Varenicline (Tyrvaya)

Reference Number: PA.CP.PMN.273
Effective Date: 01.2022
Last Review Date: 01.2022 Revision Log

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.

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 PA Health & Wellness® 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 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. Dose does not exceed 2 nasal spray bottles per 30 days.

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

II. Continued Therapy

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

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
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 PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.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 PA.CP.PMN.53.

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
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

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. 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.	01.2022	