MEDICAL MUTUAL®

Drug Policy

Policy:	Tyrvaya (varenicline nasal solution)	Annual Review Date: 04/18/2024 Last Revised Date: 04/18/2024

OVERVIEW

Tyrvaya, a cholinergic agonist, is indicated for the treatment of the signs and symptoms of **dry eye disease**. The safety and efficacy of Tyrvaya in pediatric patients have not been established.

Guidelines

The American Academy of Ophthalmology (AAO) published a Preferred Practice Pattern (2018) for the treatment of dry eye syndrome.[2] Tyrvaya is not addressed in these guidelines. The AAO classifies dry eye as mild, moderate, or severe, based on signs and symptoms of the disease. Treatment recommendations for dry eye disease are listed in a four-step progression; however, specific therapies may be chosen from any category, regardless of the level of disease severity, depending on provider experience and patient preference. For mild dry eyes, education and environmental modifications, artificial tear solutions, and eyelid therapy (warm compresses and eyelid scrubs) are listed as some of the treatment options. Medications such as an ophthalmic cyclosporine product (Restasis®, Cequa™) or Xiidra® (lifitegrast ophthalmic solution) are recommended in moderate dry eye disease.

POLICY STATEMENT

This policy involves the use of Tyrvaya. Prior authorization is recommended for pharmacy benefit coverage of Tyrvaya. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Tyrvaya as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Tyrvaya be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Tyrvaya is recommended in those who meet the following criteria:

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FDA-Approved Indication

1. **Dry Eye Disease (e.g., dry eye syndrome)**
   Criteria. *Patient must meet the following criteria (A, B, C and D):*

   A) Patient is ≥ 18 years of age; AND
   B) The provider has administered testing for one of the following homeostasis markers with corresponding results (a, b, c, or d):
      i. Schirmer's test (< 5 mm of wetting over 5 minutes), OR
      ii. Non-invasive tear breakup time (< 10 s), OR
      iii. Osmolarity (≥ 300 mOsm/L in either eye or interocular difference of > 8 mOsm/L), OR
      iv. Ocular surface staining (> 5 corneal spots, > 9 conjucntival spots, or lid margin [≥ 2 mm length and ≥ 25% width]); AND
   C) Patient has tried artificial tears; AND
   D) The medication is prescribed by or in consultation with an ophthalmologist, optometrist, or rheumatologist.

Dry Eye Disease (e.g. dry eye syndrome), Continuation of Therapy.
Criteria. *Patient must meet the following criteria*

A. The patient is 18 years of age or older; AND
B. The medication is prescribed by or in consultation with an ophthalmologist optometrist, or rheumatologist; AND
C. The patient has had a beneficial response to therapy, including reduced eye irritation, dryness, red eyes, or burning).

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Tyrvaya has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. **Concomitant use with an ophthalmic cyclosporine product, Miebo (perfluorohexyloctane ophthalmic solution), or Xiidra® (lifitegrast ophthalmic solution).** There are no data to support the concomitant use of Tyrvaya with an ophthalmic cyclosporine product, Miebo, or Xiidra.
   Note: Ophthalmic cyclosporine products are Cequa, Restasis, and Vevye.

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:
The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Tyrvaya™ nasal solution [prescribing information]. Princeton, NJ: Oyster Point Pharma; February 2024.
2. Akpek E, Amescua G, Farid M, et al. American Academy of Ophthalmology Preferred Practice Pattern Cornea and External Disease Panel. Dry Eye Syndrome Preferred Practice Pattern®. *Ophthalmology*. 2019 Jan;126(1):286-334.