

## PRIOR AUTHORIZATION POLICY

**POLICY:** Ophthalmology – Dry Eye Disease – Tyrvaya Prior Authorization Policy

- Tyrvaya™ (varenicline nasal solution – Oyster Point Pharma)

**REVIEW DATE:** 11/03/2021

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### OVERVIEW

Tyvaya, a cholinergic agonist, is indicated for the treatment of the signs and symptoms of **dry eye disease**.<sup>1</sup> The pivotal trials for Tyrvaya enrolled patients with an anesthetized Schirmer's test score within the range of 0 to 10 mm. 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.<sup>2</sup> 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

Prior Authorization is recommended for prescription benefit coverage of Tyrvaya. All approvals are provided for the duration noted below.

**Automation:** None.

### RECOMMENDED AUTHORIZATION CRITERIA

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

#### FDA-Approved Indication

1. **Dry Eye Disease (e.g., dry eye syndrome).** Approve for 1 year if the patient meets the ALL of the following (A, B, C, and D):
    - A) Patient is  $\geq 18$  years of age; AND
    - B) Patient has an anesthetized Schirmer's test score  $\leq 10$  mm; AND
    - C) Patient has tried artificial tears; AND
    - D) The medication is prescribed by or in consultation with an ophthalmologist or optometrist.
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**CONDITIONS NOT RECOMMENDED FOR APPROVAL**

Coverage of Tyrvaya is not recommended in the following situations:

1. **Concomitant use with an ophthalmic cyclosporine product (Restasis<sup>®</sup>, Cequa<sup>™</sup>) or Xiidra<sup>®</sup> (lifitegrast ophthalmic solution).** There are no data to support the concomitant use of Restasis, Cequa, or Xiidra with Tyrvaya.
2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

**REFERENCES**

1. Tyrvaya<sup>™</sup> nasal solution [prescribing information]. Princeton, NJ: Oyster Point Pharma; October 2021.
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<sup>®</sup>. *Ophthalmology*. 2019 Jan;126(1):286-334.

**HISTORY**

Type of Revision	Summary of Changes	Review Date
New Policy	--	11/03/2021