PRIOR AUTHORIZATION POLICY

POLICY: Ophthalmology – Dry Eye Disease – Tyrvaya Prior Authorization Policy
- Tyrvaya® (varenicline nasal solution – Oyster Point)

REVIEW DATE: 04/10/2024

OVERVIEW

Tyrvaya, a cholinergic agonist, is indicated for the treatment of the signs and symptoms of **dry eye disease**.[1] The safety and efficacy of Tyrvaya in pediatric patients have not been established.

Guidelines

The American Academy of Ophthalmology (AAO) Dry Eye Syndrome Preferred Practice Pattern® (2024) notes dry eye syndrome is also known as dry eye disease or keratoconjunctivitis sicca.[2] Dry eye is generally classified according to both symptoms and signs (i.e., mild, moderate, or severe); however, there is an emphasis on symptoms over signs. Management of dry eye is listed as a four-step staged approach, but specific therapies may be chosen from any step, regardless of the level of disease severity, depending on provider experience and patient preference. Tyrvaya, as well as other FDA-approved therapies for dry eye disease (cyclosporine ophthalmic products, Miebo™ [perfluorohexyloctane ophthalmic solution], and Xiidra® [lifitegrast ophthalmic solution]), are noted as Step 2 options in the Preferred Practice Pattern. The AAO notes use of any of these FDA-approved products may lead to improvement of patient symptoms and/or signs but none has been proven more effective than the other in head-to-head trials; there are no direct comparisons in a prospective clinical trial in the literature.

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.** Approve for 1 year if the patient meets the ALL of the following (A, B, and C):
   Note: Examples of dry eye disease include dry eye syndrome and keratoconjunctivitis sicca.
   A) Patient is ≥ 18 years of age; AND
   B) Patient has tried artificial tears; AND
   C) The medication is prescribed by or in consultation with an ophthalmologist or optometrist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Tyrvaya is not recommended in the following situations:

1. **Concomitant Use With An Ophthalmic Cyclosporine Product or Xiidra® (lifitegrast ophthalmic solution).** There are no data to support the concomitant use of Tyrvaya with an ophthalmic cyclosporine product 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.

REFERENCES

1. Tyrvaya™ nasal solution [prescribing information]. Princeton, NJ: Oyster Point; February 2024.
2. Amescua G, Ahmad S, Cheung AY, et al. American Academy of Ophthalmology Preferred Practice Pattern Cornea and External Disease Panel. Dry Eye Syndrome Preferred Practice Pattern®. *Ophthalmology*. 2024;131(4);P1-.