PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 04/10/2024

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

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.

- **Tyrvaya® (varenicline nasal solution (Oyster Point)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

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 COVERED

- **Tyrvaya® (varenicline nasal solution (Oyster Point)**

is(are) considered experimental, investigational or unproven for ANY other use(s) including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

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.

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-.

HISTORY

Type of Revision	Summary of Changes	Review Date
Early Annual Revision	**Dry Eye Disease:** An example of dry eye disease was moved to a Note. **Conditions Not Covered** : Concomitant use with an Ophthalmic Cyclosporine Product was revised to Concomitant Use With An Ophthalmic Cyclosporine Product,	09/20/2023

	Miebo (perfluorohexyloctane ophthalmic solution), or Xiidra (lifitegrast ophthalmic solution. The list of ophthalmic cyclosporine products was moved to a Note.	
Early Annual Revision	**Dry Eye Disease:** Keratoconjunctivitis sicca was added to the Note of examples of dry eye disease. **Conditions Not Covered** : Miebo was removed from "Concomitant Use With An Ophthalmic Cyclosporine Product, Miebo (perfluorohexyloctane ophthalmic solution), or Xiidra (lifitegrast ophthalmic solution)" because Tyrvaya can be used concomitantly with Miebo.	04/10/2024