PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 09/20/2023

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. 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) 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

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.
   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, 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.

REFERENCES

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

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	11/02/2022

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, Miebo (perfluorohexyloctane ophthalmic solution), or Xiidra (lifitegrast ophthalmic solution. The list of ophthalmic cyclosporine products was moved to a Note.	09/20/2023