Drug Coverage Policy

Effective Date.....7/15/2025
Coverage Policy Number.....IP0395
Policy Title.....Tyrvaya

Ophthalmology – Dry Eye Disease – Tyrvaya for Individual and Family Plans

- Tyrvaya® (varenicline nasal solution - Oyster Point)

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 where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. 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.

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.

Coverage Policy

Policy Statement
Prior Authorization is recommended for prescription benefit coverage of Tyrvaya. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. 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, approval requires Tyrvaya to be prescribed by a physician who has consulted with or who specializes in the condition.

Tyrvaya is considered medically necessary when the following is met:

FDA-Approved Indication

1. **Dry Eye Disease.** Approve for 1 year if the patient meets the ALL of the following (A, B, C, and D):
   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.
   D) Preferred product criteria is met for the product(s) as listed in the below table(s)

Individual and Family Plans:

Product	Criteria
Tyrvaya (varenicline tartrate 0.03 mg/actuation nasal solution)	Patient has tried, and according to the prescriber, has experienced inadequate efficacy OR significant intolerance with cyclosporine ophthalmic 0.05% emulsion

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Conditions Not Covered

Tyrvaya for any other use is considered not medically necessary, including the following (this list may not be all inclusive; criteria will be updated as newly 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-P49.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	IFP added to the policy Employer Plans removed from the policy. **Added** diagnosis, age, a previous use of artificial tears and specialist prescribing requirement. **Updated** preferred product requirements. **Conditions Not Recommended for Approval:** 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.	8/1/2024
Annual Revision	No criteria changes.	7/15/2025

The policy effective date is in force until updated or retired.