Effective Date **1/15/2024**
Next Review Date… **1/15/2025**
Coverage Policy Number **IP0395**

Varenicline Nasal Solution

Table of Contents

Related Coverage Resources

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.

Overview

This policy supports medical necessity review for formulary exceptions for varenicline nasal solution (**Tyrvaya**™).

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

Medical Necessity Criteria

Coverage criteria are listed for products listed **in below table:**

Non-Covered Product	Criteria
Tyrvaya (varenicline tartrate 0.03 mg/actuation nasal solution)	**Tyrvaya is medically necessary when there is documentation of failure, contraindication, or intolerance to BOTH of the following:** 1. **ONE** of the following: a. cyclosporine 0.05% ophthalmic emulsion b. Cequa™ (cyclosporine 0.09% ophthalmic solution) 2. Xiidra® (lifitegrast 5% ophthalmic solution)

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.

Reauthorization Criteria

Continuation of varenicline nasal solution (Tyrvaya) is considered medically necessary when the above medical necessity criteria are met **AND** there is documentation of beneficial response.

Authorization Duration

Initial and Reauthorization approval duration: up to 12 months

Conditions Not Covered

Any other use is considered experimental, investigational or unproven, including the following (this list may not be all inclusive):

- **Concomitant use with an ophthalmic cyclosporine product (Cequa, Restasis, Vevye), 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.

Background

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.

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.