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Section:	Prescription Drugs	**Effective Date:**	April 1, 2025
Subsection:	Topical Products	**Original Policy Date:**	November 5, 2021
Subject:	Tyrvaya	**Page:**	1 of 5

Last Review Date: March 7, 2025

Tyrvaya

Description

Tyrvaya (varenicline solution)

Background
Tyrvaya (varenicline solution) is a nicotinic acetylcholine receptor agonist. Stimulation of this receptor produces activity in the trigeminal parasympathetic pathway and promotes the production of basal tear film as a treatment for dry eye disease. The exact mechanism of action is unknown currently (1).

Dry eye disease is a common pathology that can result from different dysfunctions in the tear film production pathway. The tear film is made up of distinct phases including an aqueous phase mucin phase and a lipid layer which are produced by the lacrimal and meibomian glands. Both glands are innervated by parasympathetic and sympathetic fibers and provide a basal rate of tear production that is produced throughout the day to lubricate and protect the eye from infection. Dry eye can result from inflammation interfering with the production of tear film, or improper mixture of tear components can lead to tears that evaporate more quickly than they can be replaced (1).

Regulatory Status
FDA-approved indication: Tyrvaya (varenicline solution) nasal spray is a cholinergic agonist indicated for the treatment of the signs and symptoms of dry eye disease (1).

The safety and effectiveness of Tyrvaya in pediatric patients have not been established (1).

Related policies

Cyclosporine Ophthalmics, Eysuvis, Xiidra

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Tyrvaya may be considered **medically necessary** if the conditions indicated below are met.

Tyrvaya may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

1. Dry eye disease
    a. Inadequate treatment response, intolerance, or contraindication to a legend ophthalmic for the treatment of dry eyes (see Appendix 1)
    b. **NO** dual therapy with another legend ophthalmic for the treatment of dry eyes (see Appendix 1)

Prior–Approval *Renewal* Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

1. Dry eye disease
    a. Patient has had an improvement in symptoms

b. **NO** dual therapy with another legend ophthalmic for the treatment of dry eyes (see Appendix 1)

Policy Guidelines

Pre–PA Allowance

None

Prior–Approval Limits

Quantity 6 nasal spray bottles per 90 days

Duration 12 months

Prior–Approval *Renewal* Limits

Same as above

Rationale

Summary

Tyrvaya (varenicline solution) is a nasal spray indicated for the treatment of dry eye disease. Although the exact mechanism of action is not known, the medication does agonize the nicotinic acetylcholine receptor of the parasympathetic pathway. Stimulation of this receptor pathway is thought to increase the basal rate of tear production from the lacrimal and meibomian glands. The safety and effectiveness of Tyrvaya in pediatric patients have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Tyrvaya while maintaining optimal therapeutic outcomes.

References

1. Tyrvaya [package insert]. Princeton, NJ: Oyster Point Pharma, Inc.; February 2024.

Policy History

Date	Action
November 2021	Addition to PA
December 2021	Annual review
March 2022	Annual review
June 2022	Per FEP, addition of requirement to t/f a legend ophthalmic for dry eyes
September 2022	Annual review
March 2023	Annual review
December 2023	Annual review
March 2024	Annual review
March 2025	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 7, 2025 and is effective on April 1, 2025.

Appendix 1 - List of Legend Ophthalmic Medications for Dry Eye

Generic Name	Brand Name
cyclosporine	Cequa
cyclosporine	Restasis
cyclosporine	Vevye
lifitegrast	Xiidra
loteprednol	Eysuvis
perfluorohexyloctane	Miebo
varenicline	Tyrvaya

*Verkazia is not approved for dry eye