

TYRVAYA (varenicline solution)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Tyrvaya (varenicline solution) is a nicotinic acetylcholine receptor agonist. Stimulation of this receptor Tyrvaya 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).

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.