

Varenicline (TYRVAYA) Nasal Spray

Criteria for Use

November 2022

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

See the VA National PBM-MAP-VPE Monograph on this drug at the [PBM INTRAnet](#) site for further information.

Exclusion Criteria

- Nasal or sinus conditions that may interfere with administration

Inclusion Criteria

All of the following criteria must be met

- Provider is a VA/VA Community Care ophthalmologist or optometrist
- Diagnosis of dry eye disease
- Documented lack of therapeutic response to at least two artificial tear agents from different categories OR documented corneal surface damage while frequently using artificial tear agent(s)¹
- Lack of response to an adequate trial of ophthalmic cyclosporine unless unable to use (e.g., intolerance, etc.)²
- Lack of response to an adequate trial of lifitegrast unless unable to use (e.g., intolerance, etc.)²

1. Examples of Product Categories (not all-inclusive; not all are on VA Formulary):

- A. Cellulose Derivatives (e.g., carboxymethylcellulose, hydroxypropyl methylcellulose/hypromellose)
- B. Liquid Polyols (e.g., polyethylene glycol (PEG), propylene glycol, glycerin)
- C. Polyvinyl Alcohol
- D. Oil containing (e.g., mineral oil, castor oil, flaxseed oil) E. High Viscosity: gel drops, gels, ointments

2. With cyclosporine, it can take **3 to 6 months** to notice an increase in tear production or improved symptoms. Symptom relief with lifitegrast may begin as early as 2 weeks with general improvements at 6 and 12 weeks

Note: Patients with punctal or intracanalicular occlusion were excluded from the clinical trials.

Other Justification

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Contact: Deb Khachikian, PharmD National Clinical Pharmacy Program Manager, VA Pharmacy Benefits Management Services (12PBM)
