

Tyrvaya (varenicline) Nasal Solution

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Tyrvaya (varenicline tartrate) Nasal Solution	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Tyrvaya (varenicline tartrate) Nasal Solution may be approved if the following criteria are met:

- I. Individual is 18 years of age or older;

AND

- II. Individual is using to treat moderate to severe dry eye disease (AAO 2018); **AND**
- III. Individual had an abnormal result or response to one or more of the following dry eye disease diagnostic/assessment methods (AAO 2018):
 - A. Tear break-up time (less than 10 seconds); **OR**
 - B. Ocular surface dye staining using fluorescein, rose bengal, or lissamine green dyes; **OR**
 - C. Schirmer test (aqueous tear production of less than or equal to 10 mm of strip wetting in 5 minutes); **OR**
 - D. Fluorescein clearance test/tear function index; **OR**
 - E. Tear osmolarity (indicating tear film instability); **OR**
 - F. Tear lactoferrin concentrations in the lacrimal gland (decreased); **OR**
 - G. Matrix metalloproteinase-9 (MMP-9) test;

AND

- IV. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to Xiidra (lifitegrast ophthalmic solution); **OR**
- V. Individual has a known hypersensitivity to any ingredient in Xiidra which is not also present in the requested non-preferred agent (Tyrvaya).

Key References:

1. American Academy of Ophthalmology Cornea/External Disease Panel. Preferred Practice Pattern Guidelines. Dry Eye Syndrome. San Francisco, CA: American Academy of Ophthalmology; 2018. Available at: <https://www.aao.org/preferred-practice-pattern/dry-eye-syndrome-ppp-2018>. Accessed: January 11, 2023.

2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: January 11, 2023.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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