Virginia Department of Health Professions
Board of Optometry

Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, VA 23233-1463

Email: optbd@dhp.virginia.gov
Phone: (804) 597-4132
Fax: (804) 527-4471
Website: https://www.dhp.virginia.gov/Boards/Optometry/

January 28, 2022
Board Room 2
2:00 p.m.

Agenda

Virginia Board of Optometry
TPA-Formulary Committee Meeting

Call to Order – Lisa Wallace-Davis, O.D., Board President **Page 1**

- Welcome
- Emergency Egress Procedures
- Introductions
- Mission Statement

Ordering of Agenda – Dr. Wallace-Davis

Public Comment – Dr. Wallace-Davis
The Board will receive all public comment related to agenda items at this time. The Board will not receive comment on any regulatory process for which a public comment period has closed or any pending or closed complaint or disciplinary matter.

Discussion Items **Pages 2-31**
Consideration of the addition of two therapeutic drugs to TPA-Formulary

- Pilocarpine hydrochloride ophthalmic solution 1.25%,, a muscarinic receptor agonist, for treatment of presbyopia in adults (pages 2-15)
- Varenicline solution nasal spray, a cholinergic agonist, for treatment of signs and symptoms of dry eye disease (pages 16-26)

Next Steps – Dr. Wallace-Davis/Leslie Knachel/Elaine Yeatts

Meeting Adjournment – Dr. Wallace-Davis

This information is in **DRAFT** form and is subject to change.

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MISSION STATEMENT

Our mission is to ensure safe and competent patient care by licensing health professionals, enforcing standards of practice, and providing information to health care practitioners and the public.

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use VUITY safely and effectively. See full prescribing information for VUITY.

VUITY (pilocarpine hydrochloride ophthalmic solution) 1.25%, for topical ophthalmic use
Initial U.S. Approval: 1974

----------INDICATIONS AND USAGE----------
VUITY is a cholinergic muscarinic receptor agonist indicated for the treatment of presbyopia in adults. (1)

----------DOSAGE AND ADMINISTRATION----------
Instill one drop of VUITY in each eye once daily. (2)

----------DOSAGE FORMS AND STRENGTHS----------
Ophthalmic solution containing pilocarpine hydrochloride 1.25%. (3)

----------CONTRAINDICATIONS----------
Hypersensitivity (4)

----------WARNINGS AND PRECAUTIONS----------
Poor Illumination: Exercise caution in night driving and other hazardous occupations in poor illumination. (5.1)
Risk of Retinal Detachment: Rare cases of retinal detachment have been reported with other miotics; patients should be advised to seek immediate medical care with sudden onset of vision loss. (5.2)
Iritis: Caution is advised in patients with iritis. (5.3)

----------ADVERSE REACTIONS----------
Most common adverse reactions (>5%) are headache and conjunctival hyperemia. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Allergan at 1-800-678-1605 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION

Revised: 10/2021

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

VUITY is indicated for the treatment of presbyopia in adults.

2 DOSAGE AND ADMINISTRATION

The recommended dosage of VUITY is one drop in each eye once daily.

If more than one topical ophthalmic product is being used, the products should be administered at least 5 minutes apart.

3 DOSAGE FORMS AND STRENGTHS

VUITY (pilocarpine hydrochloride ophthalmic solution) is provided as a 1.25% solution (12.5 mg/mL).

4 CONTRAINDICATIONS

VUITY is contraindicated in patients with known hypersensitivity to the active ingredient or to any of the excipients.

5 WARNINGS AND PRECAUTIONS

5.1 Poor Illumination

Patients should be advised to exercise caution in night driving and other hazardous occupations in poor illumination. In addition, miotics may cause accommodative spasm. Patients should be advised not to drive or use machinery if vision is not clear.

5.2 Risk of Retinal Detachment

Rare cases of retinal detachment have been reported with other miotics when used in susceptible individuals and those with pre-existing retinal disease. Patients should be advised to seek immediate medical care with sudden onset of vision loss.

5.3 Iritis

VUITY is not recommended to be used when iritis is present because adhesions (synechiae) may form between the iris and the lens.

5.4 Use with Contact Lenses

Contact lens wearers should be advised to remove their lenses prior to the instillation of VUITY and to wait 10 minutes after dosing before reinserting their contact lenses.

5.5 Potential for Eye Injury or Contamination

To prevent eye injury or contamination, care should be taken to avoid touching the dispensing bottle to the eye or to any other surface.

6 ADVERSE REACTIONS

The following clinically significant adverse reactions are described elsewhere in labeling:

- Hypersensitivity *[see Contraindications (4)]*

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

VUITY was evaluated in 375 patients with presbyopia in two randomized, double-masked, vehicle-controlled studies (GEMINI 1 and GEMINI 2) of 30 days duration. The most common adverse reactions reported in >5% of patients were headache and conjunctival hyperemia. Ocular adverse reactions reported in 1-5% of patients were blurred vision, eye pain, visual impairment, eye irritation, and increased lacrimation.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no adequate and well-controlled studies of VUITY administration in pregnant women to inform a drug-associated risk. Oral administration of pilocarpine to pregnant rats throughout organogenesis and lactation did not produce adverse effects at clinically relevant doses.

Data

Human Data

No adequate and well-controlled trials of VUITY have been conducted in pregnant women. In a retrospective case series of 15 women with glaucoma, 4 patients used ophthalmic pilocarpine either pre-pregnancy, during pregnancy or postpartum. There were no adverse effects observed in patients or in their infants.

Animal Data

In embryofetal development studies, oral administration of pilocarpine to pregnant rats throughout organogenesis produced maternal toxicity, skeletal anomalies and reduction in fetal body weight at 90 mg/kg/day (approximately 970-fold higher than the maximum recommended human ophthalmic dose [MRHOD] of 0.015 mg/kg/day, on a mg/m^2 basis).

In a peri-/postnatal study in rats, oral administration of pilocarpine during late gestation through lactation increased stillbirths at a dose of 36 mg/kg/day (approximately 390-fold higher than the MRHOD). Decreased neonatal survival and reduced mean body weight of pups were observed at ≥18 mg/kg/day (approximately 200 times the recommended human daily dose of VUITY).

8.2 Lactation

Risk Summary

There is no information regarding the presence of pilocarpine in human milk, the effects on the breastfed infants, or the effects on milk production to inform risk of VUITY to an infant during lactation.

Pilocarpine and/or its metabolites are excreted in the milk of lactating rats. Systemic levels of pilocarpine following topical ocular administration are low *[see Clinical Pharmacology (12.3)]*, and it is not known whether measurable levels of pilocarpine would be present in maternal milk following topical ocular administration.

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for VUITY and any potential adverse effects on the breastfed child from VUITY.

Data
Animal Data
Following a single oral administration of ^{14}C-pilocarpine to lactating rats, the radioactivity concentrations in milk were similar to those in plasma.

8.4 Pediatric Use

Presbyopia does not occur in the pediatric population.

8.5 Geriatric Use

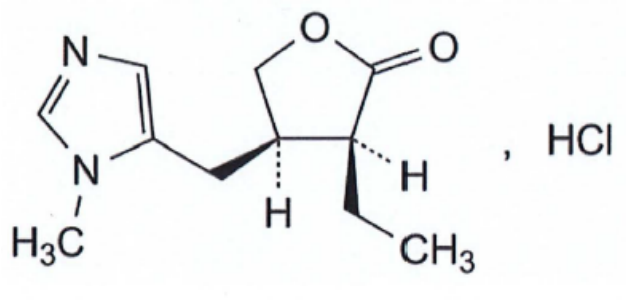
Clinical studies of VUITY did not include subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience with ophthalmic pilocarpine solutions have not identified overall differences in safety between elderly and younger patients.

10 OVERDOSAGE

Systemic toxicity following topical ocular administration of pilocarpine is rare, but occasionally patients who are sensitive may develop sweating and gastrointestinal overactivity. Accidental ingestion can produce sweating, salivation, nausea, tremors and slowing of the pulse and a decrease in blood pressure. In moderate overdosage, spontaneous recovery is to be expected and is aided by intravenous fluids to compensate for dehydration. For patients demonstrating severe poisoning, atropine, the pharmacologic antagonist to pilocarpine, should be used.

11 DESCRIPTION

VUITY (pilocarpine hydrochloride ophthalmic solution) 1.25% is a cholinergic muscarinic receptor agonist prepared as an isotonic, colorless, sterile ophthalmic solution containing 1.25% of pilocarpine hydrochloride. The chemical name for pilocarpine hydrochloride is (3S,4R)-3-ethyl-4-[(1-methyl-1H-imidazol-5-yl)methyl]oxolan-2-one hydrochloride. Its molecular weight is 244.72 and its molecular formula is $C_{11}H_{16}N_2O_2 \cdot HCl$. Its structural formula is:



Each mL of VUITY contains pilocarpine hydrochloride 1.25% (12.5 mg) as the active ingredient, equivalent to 1.06% (10.6 mg) pilocarpine free-base. Preservative is: benzalkonium chloride 0.0075%. Inactive ingredients in the ophthalmic solution are: boric acid, sodium citrate dihydrate, sodium chloride, purified water, and may also include hydrochloric acid and/or sodium hydroxide for pH adjustment to between 3.5 and 5.5, if necessary.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Pilocarpine hydrochloride is a cholinergic muscarinic agonist which activates muscarinic receptors located at smooth muscles such as the iris sphincter muscle and ciliary muscle. VUITY contracts the iris sphincter muscle, constricting the pupil to improve near and intermediate visual acuity while maintaining some pupillary response to light. VUITY also contracts the ciliary muscle and may shift the eye to a more myopic state.

12.3 Pharmacokinetics

Systemic exposure to pilocarpine was evaluated in 22 participants with presbyopia who were administered 1 drop of VUITY in each eye once daily for 30 days. The mean C_{max} and $AUC_{0\text{-}t,ss}$ values on Day 30 were 1.95 ng/mL and 4.14 ng·hr/mL, respectively. The median T_{max} value on Day 30 was 0.3 hours postdose with a range from 0.2 to 0.5 hours postdose.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis
Pilocarpine did not induce tumors in mice at any dosage level studied (up to 30 mg/kg/day; approximately 160-times the MRHOD). In rats, an oral dose of 18 mg/kg/day (approximately 200 times the MRHOD), resulted in a statistically significant increase in the incidence of benign pheochromocytomas in both male and female rats, and a statistically significant increase in the incidence of hepatocellular adenomas in female rats.

Mutagenesis
Pilocarpine did not show any potential to cause genetic toxicity in a series of studies that included: 1) bacterial assays (Salmonella and E. coli) for reverse gene mutations; 2) an in vitro chromosome aberration assay in a Chinese hamster ovary cell line; 3) an in vivo chromosome aberration assay (micronucleus test) in mice; and 4) a primary DNA damage assay (unscheduled DNA synthesis) in rat hepatocyte primary cultures.

Impairment of Fertility
Pilocarpine oral administration to male and female rats at a dosage of 18 mg/kg/day (200 times the recommended human daily dose) resulted in impaired reproductive function, including reduced fertility, decreased sperm motility, and morphologic evidence of abnormal sperm. It is unclear whether the reduction in fertility was due to effects on males, females, or both. In dogs, exposure to pilocarpine at a dosage of 3 mg/kg/day for 6 months resulted in evidence of impaired spermatogenesis (approximately 110 times the recommended human daily dose).

14 CLINICAL STUDIES

The efficacy of VUITY for the treatment of presbyopia was demonstrated in two 30-Day Phase 3, randomized, double-masked, vehicle-controlled studies, namely GEMINI 1 (NCT03804268) and GEMINI 2 (NCT03857542). A total of 750 participants aged 40 to 55 years old with presbyopia were randomized (375 to VUITY group) in two studies and participants were instructed to administer one drop of VUITY or vehicle once daily in each eye.

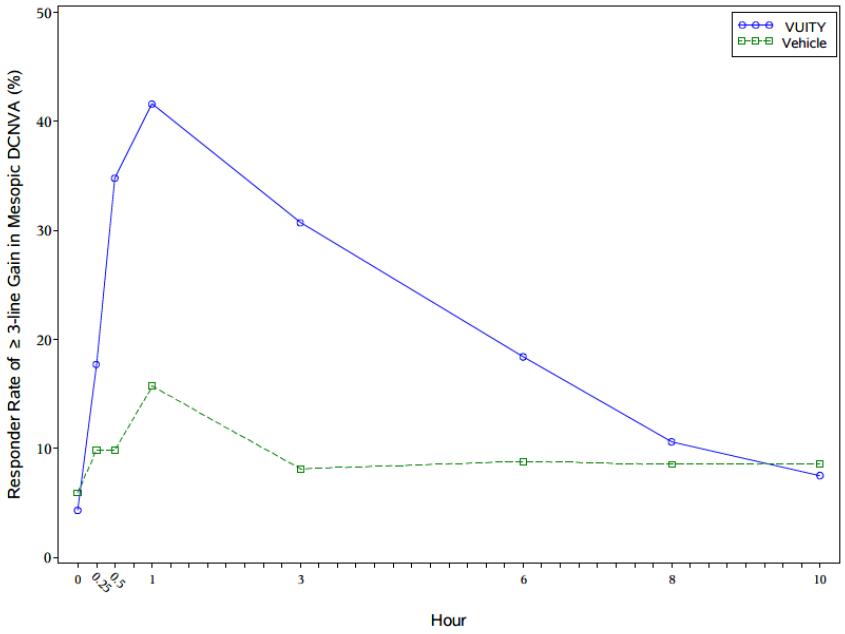
In both studies, the proportion of participants gaining 3 lines or more in mesopic, high contrast, binocular distance corrected near visual acuity (DCNVA), without losing more than 1 line (5 letters) of corrected distance visual acuity (CDVA) with the same refractive correction was statistically significantly greater in the VUITY group compared to the vehicle group at Day 30, Hour 3 (see Table 1).

Table 1: Primary Efficacy Results from GEMINI 1 and GEMINI 2 Studies (Intent-to-Treat Population)

	GEMINI 1			GEMINI 2		
	VUITY N=163	Vehicle N=160	p-value	VUITY N=212	Vehicle N=215	p-value
Proportion of participants gaining 3-lines or more in mesopic DCNVA, without losing more than 1 line (5 letters) of CDVA at Day 30, Hour 3	31%	8%	p<0.01	26%	11%	p<0.01

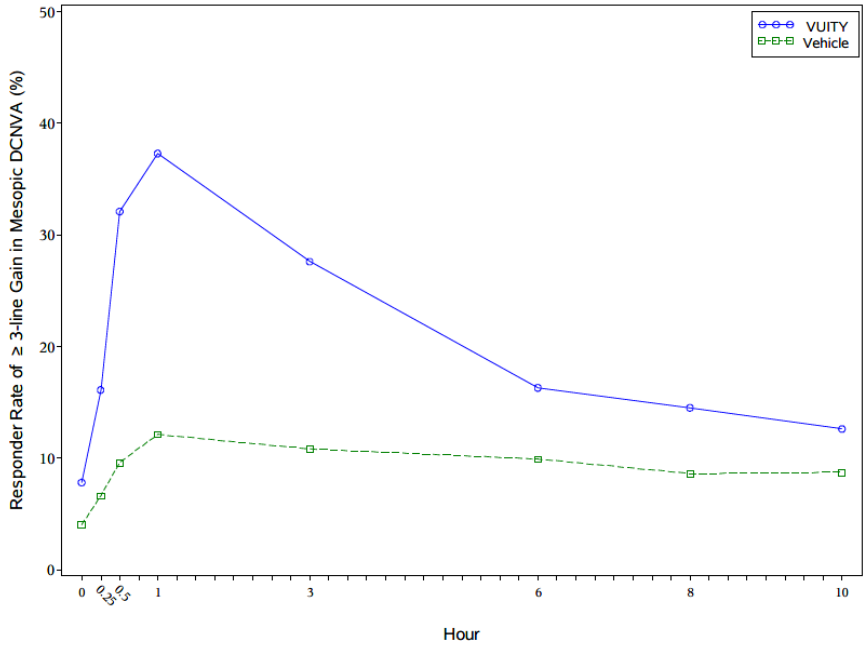
Figures 1 and 2 present the proportion of participants who gained 3-lines or more in mesopic DCNVA at Day 30.

Figure 1: Proportion of Participants Achieving 3-Lines or More Improvement in Mesopic, High Contrast, Binocular DCNVA at Day 30 in GEMINI 1 (Intent-to-Treat Population)



Timepoint	Hour 0	Hour 0.25	Hour 0.5	Hour 1	Hour 3	Hour 6	Hour 8	Hour 10
VUITY (%)	4.3	17.7	34.8	41.6	30.7	18.4	10.6	7.5
Vehicle (%)	5.9	9.8	9.8	15.7	8.1	8.8	8.5	8.6
Difference (95% CI)	-1.5 (-6.4, 3.3)	7.9 (0.3, 15.5)	25.0 (16.2, 33.8)	25.9 (16.4, 35.5)	22.5 (14.3, 30.8)	9.7 (2.3, 17.0)	2.1 (-4.4, 8.5)	-1.1 (-7.1, 5.0)

Figure 2: Proportion of Participants Achieving 3-lines or More Improvement in Mesopic, High Contrast, Binocular DCNVA at Day 30 in GEMINI 2 (Intent-to-Treat population)



Timepoint	Hour 0	Hour 0.25	Hour 0.5	Hour 1	Hour 3	Hour 6	Hour 8	Hour 10
VUITY (%)	7.8	16.1	32.1	37.3	27.6	16.3	14.5	12.6
Vehicle (%)	4.0	6.6	9.6	12.1	10.8	9.9	8.6	8.7
Difference (95% CI)	3.8 (-0.9, 8.4)	9.4 (3.2, 15.7)	22.5 (14.7, 30.3)	25.2 (17.0, 33.4)	16.7 (9.1, 24.3)	6.5 (-0.1, 13.1)	5.9 (-0.5, 12.2)	3.8 (-2.3, 10.0)

16 HOW SUPPLIED/STORAGE AND HANDLING

VUITY is supplied as a sterile ophthalmic solution in colorless low density polyethylene (LDPE) ophthalmic dispenser bottles and tips, with dark green high impact polystyrene caps as follows:

2.5 mL fill in 5 mL bottle (Box containing 1 bottle)	NDC 0074-7098-01
2.5 mL fill in 5 mL bottle (Box containing 3 bottles)	NDC 0074-7098-03
2.5 mL fill in 5 mL bottle (Carton)	NDC 0074-7098-04

Storage

Store at 15°C to 25°C (59°F to 77°F). After opening, VUITY can be used until the expiration date on the bottle.

17 PATIENT COUNSELING INFORMATION

Night Driving
Caution is advised with night driving and when hazardous activities are undertaken in poor illumination. *[see Warnings and Precautions (5.1)]*

Accommodative Spasm
Temporary problems when changing focus between near objects and distant objects may occur. Advise patients not to drive or use machinery if vision is not clear. *[see Warnings and Precautions (5.1)]*

When to Seek Physician Advice
Advise patients to seek immediate medical care with sudden onset of vision loss. *[see Warnings and Precautions (5.2)]*

Contact Lens Wear
Contact lens should be removed prior to the instillation of VUITY. Wait 10 minutes after dosing before reinserting contact lenses. *[see Warnings and Precautions (5.4)]*

Avoiding Contamination of the Product
Do not touch dropper tip to any surface, as this may contaminate the contents. *[see Warnings and Precautions (5.5)]*

Concomitant Topical Ocular Therapy
If more than one topical ophthalmic medication is being used, the medicines must be administered at least 5 minutes apart.

Distributed by: Allergan, an AbbVie Company
Manufactured for:
AbbVie Inc.
North Chicago, IL 60064 USA
Allergan is an affiliate of AbbVie Inc.

Comment on a Petition for Rulemaking

Promulgating Board: **Board of Optometry**

Regulatory Coordinator: Elaine J. Yeatts
(804)367-4688
elaine.yeatts@dhp.virginia.gov

Agency Contact: Leslie L. Knachel
Executive Director
(804)597-4130
leslie.knachel@dhp.virginia.gov

Contact Address: Department of Health Professions
9960 Mayland Drive
Suite 300
Richmond, VA 23233

Chapter Affected:

18 vac 105 - 20: **Regulations of the Virginia Board of Optometry**

Statutory Authority: State: Chapter 32 of Title 54.1

Date Petition Received 05/06/2021

Petitioner Weston Pack

Petitioner's Request

To add an investigative ophthalmic drop to the approved formulary of drugs that may be prescribed by an optometrist

Agency Plan

In accordance with Virginia law, the petition has been filed with the Register of Regulations and will be published on June 7, 2021. Comment on the petition may be sent by email, regular mail or posted on the Virginia Regulatory Townhall at www.townhall.virginia.gov; comment will be requested until July 7, 2021. Following receipt of all comments on the petition to amend regulations, the Board will decide whether to make any changes to the regulatory language. This matter will be on the Board's agenda for its next meeting scheduled for July 16, 2021, and the petitioner will be informed of the Board's decision after that meeting.

Publication Date 06/07/2021 *(comment period will also begin on this date)*

Comment End Date 07/07/2021

COMMONWEALTH OF VIRGINIA
Board of Optometry

9960 Mayland Drive, Suite 300
Henrico, Virginia 23233-1463

(804) 367-4508 (Tel)
(804) 527-4466 (Fax)

Petition for Rule-making

The Code of Virginia (§ 2.2-4007) and the Public Participation Guidelines of this board require a person who wishes to petition the board to develop a new regulation or amend an existing regulation to provide certain information. Within 14 days of receiving a valid petition, the board will notify the petitioner and send a notice to the Register of Regulations identifying the petitioner, the nature of the request and the plan for responding to the petition. Following publication of the petition in the Register, a 21-day comment period will begin to allow written comment on the petition. Within 90 days after the comment period, the board will issue a written decision on the petition.

Please provide the information requested below. (Print or Type)

Petitioner's full name (Last, First, Middle initial, Suffix,)		
Pack, Weston, D		
Street Address	**Area Code and Telephone Number**	
1 N. Waukegan Road	(919) 271-7319	
City	**State**	**Zip Code**
North Chicago	IL	60064
Email Address (optional)	**Fax (optional)**	
weston.pack@abbvie.com		

Respond to the following questions:

1. What regulation are you petitioning the board to amend? Please state the title of the regulation and the section/sections you want the board to consider amending.

Addition of a new investigative ophthalmic drop for the treatment of the symptoms of presbyopia to the approved list of medications that can be prescribed by optometrists in the state of Virginia (pending FDA approval).

2. Please summarize the substance of the change you are requesting and state the rationale or purpose for the new or amended rule.

AGN-190584 (pilocarpine 1.25%) is an investigational optimized formulation of pilocarpine, a cholinergic muscarinic receptor agonist, which activates muscarinic receptors located at smooth muscles such as the iris sphincter muscle and ciliary muscle and is being investigated for the treatment of presbyopia as a topical, once-daily drop delivered by a proprietary vehicle. The proposed mechanism of action of AGN-190584 is through contraction of the iris sphincter muscle, constricting the pupil to enhance the depth of focus and improve near and intermediate visual acuity while maintaining some pupillary response to light. AGN-190584 also contracts the ciliary muscle, facilitating accommodation.

In the Phase 3 clinical trials, AGN-190584 met the primary endpoint reaching statistical significance with 3-line or greater improvement in near vision in mesopic (in low light) conditions without a loss of distance vision vs. the vehicle. The majority of secondary endpoints were also met in both studies, including a significant improvement in patient-reported outcomes (PROs) such as an increase in vision-related reading ability, and reductions in the impact of presbyopia on daily life and use of coping behaviors to manage presbyopia. There were no treatment emergent serious adverse events observed in any AGN-190584 treated participants.

3. State the legal authority of the board to take the action requested. In general, the legal authority for the adoption of regulations by the board is found in § 54.1-2400 of the Code of Virginia. If there is <u>other</u> legal authority for promulgation of a regulation, please provide that Code reference.

Leslie L. Knachel, M.P.H.
Executive Director
Board of Optometry

Signature: Weston Pack **Date:** 05/04/2021

Leslie Knachel

From: Pack, Weston D <weston.pack@abbvie.com> on behalf of Pack, Weston D
Sent: Monday, March 22, 2021 12:49 PM
To: leslie.knachel@dhp.virginia.gov
Subject: Allergan investigational presbyopia drop description

Good afternoon Leslie,

My colleague Justin Rienzo asked me to send you an email with a description of our investigational ophthalmic drop for Presbyopia. Here is a summary that we have provided to meet the requests of other state boards:

AGN-190584 (pilocarpine 1.25%) is an investigational optimized formulation of pilocarpine, a cholinergic muscarinic receptor agonist, which activates muscarinic receptors located at smooth muscles such as the iris sphincter muscle and ciliary muscle and is being investigated for the treatment of presbyopia as a topical, once-daily drop delivered by a proprietary vehicle. The proposed mechanism of action of AGN-190584 is through contraction of the iris sphincter muscle, constricting the pupil to enhance the depth of focus and improve near and intermediate visual acuity while maintaining some pupillary response to light. AGN-190584 also contracts the ciliary muscle, facilitating accommodation.

In the Phase 3 clinical trials, AGN-190584 met the primary endpoint reaching statistical significance with 3-line or greater improvement in near vision in mesopic (in low light) conditions without a loss of distance vision vs. the vehicle. The majority of secondary endpoints were also met in both studies, including a significant improvement in patient-reported outcomes (PROs) such as an increase in vision-related reading ability, and reductions in the impact of presbyopia on daily life and use of coping behaviors to manage presbyopia. There were no treatment emergent serious adverse events observed in any AGN-190584 treated participants.

I'm happy to assist if you require any further information.

Weston

Allergan
an AbbVie Company

WESTON PACK, PHD
Medical Science Liaison, Anterior Segment
Allergan Eye Care, Research and Development, AbbVie

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Agency

Department of Health Professions

Board

Board of Optometry

Chapter

Regulations of the Virginia Board of Optometry [18 VAC 105 - 20]

3 comments

6/10/21 8:26 am

Commenter: David R Rose, OD Virginia Optometric Associatio,

In favor

I am in favor of this of this new drug being added to the TPA formulary for Virginia optometrists. Optometrists in Virginia are capable and should be allowed to practice to the full scope of our training.

CommentID: 99083

6/14/21 12:39 pm

Commenter: Cynthia Hites

In support of petition

I support granting this petition

CommentID: 99106

6/22/21 11:31 pm

Commenter: Jacqueline Theis, OD, Virginia Optometric Association Board of Trustees

I am in support of this petition.

I am in support of this petition as it relates to optometrists practicing to the full scope of their state license

CommentID: 99238

Virginia.gov Agencies | Governor

Secretariat **Health and Human Resources**

Agency **Department of Health Professions**

Board **Board of Optometry**

Petition 345

Petition Information	
Petition Title	Addition of investigational drug to TPA formulary
Date Filed	5/6/2021 **[Transmittal Sheet]**
Petitioner	Weston Pack
Petitioner's Request	To add an investigative ophthalmic drop to the approved formulary of drugs that may be prescribed by an optometrist
Agency's Plan	In accordance with Virginia law, the petition has been filed with the Register of Regulations and will be published on June 7, 2021. Comment on the petition may be sent by email, regular mail or posted on the Virginia Regulatory Townhall at **www.townhall.virginia.gov**; comment will be requested until July 7, 2021. Following receipt of all comments on the petition to amend regulations, the Board will decide whether to make any changes to the regulatory language. This matter will be on the Board's agenda for its next meeting scheduled for July 16, 2021, and the petitioner will be informed of the Board's decision after that meeting.
Comment Period	Ended 7/7/2021 **3 comments**
Agency Decision	Take no action **[Transmittal Sheet]**
Response Date	7/26/2021
Agency Decision Summary	At its meeting on July 16th, the Board voted to deny the petition based on information that the drug requested is not yet approved by the Food & Drug Administration for the particular use in optometric practice. The Board will continue to monitor the process and will consider the initiation of a regulatory process when FDA approval is given.

Contact Information	
Name / Title:	Leslie L. Knachel / *Executive Director*

P014

Address:	9960 Mayland Drive Suite 300 Richmond, 23233
Email Address:	**leslie.knachel@dhp.virginia.gov**
Telephone:	(804)597-4130 FAX: (804)527-4471 TDD: ()-

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use TYRVAYA safely and effectively. See full prescribing information for TYRVAYA.

TYRVAYA™ (varenicline solution) nasal spray
Initial U.S. Approval: 2006

----------INDICATIONS AND USAGE----------
TYRVAYA (varenicline solution) nasal spray is a cholinergic agonist indicated for the treatment of the signs and symptoms of dry eye disease. (1)

----------DOSAGE AND ADMINISTRATION----------
- One spray in each nostril twice daily (approximately 12 hours apart). (2.1)
- Prime with seven (7) actuations before initial use. Re-prime with 1 actuation if not used for more than five (5) days. (2.2)

----------DOSAGE FORMS AND STRENGTHS----------
Nasal spray delivering 0.03 mg of varenicline in each spray (0.05 mL). (3)

----------CONTRAINDICATIONS----------
None.

----------ADVERSE REACTIONS----------
The most common adverse reaction reported in 82% of patients was sneezing. Events that were reported in 5-16% of patients were cough, throat irritation, and instillation-site (nose) irritation. (6)

To report SUSPECTED ADVERSE REACTIONS, contact Oyster Point Pharma at 1-877-EYE-0123 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION and FDA approved patient labeling.

Revised: 10/2021

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed.

F

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE
TYRVAYA (varenicline solution) nasal spray is indicated for the treatment of the signs and symptoms of dry eye disease.

2 DOSAGE AND ADMINISTRATION
2.1 Dosing Information
Spray TYRVAYA once in each nostril twice daily (approximately 12 hours apart). If a dose is missed, resume regular dosing at the next scheduled dose time.

2.2 Priming Instructions
Priming: Prime TYRVAYA before initial use by pumping seven (7) actuations into the air away from the face. When TYRVAYA has not been used for more than 5 days, re-prime with 1 spray into the air. Do not shake.

3 DOSAGE FORMS AND STRENGTHS
Nasal spray delivering 0.03 mg of varenicline in each spray (0.05 mL).

4 CONTRAINDICATIONS
None

6 ADVERSE REACTIONS
6.1 Clinical Trials Experience
Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

In three clinical studies of dry eye disease conducted with varenicline solution nasal spray, 349 patients received at least 1 dose of TYRVAYA. The majority of patients had 31 days of treatment exposure, with a maximum exposure of 105 days.

The most common adverse reactions reported in 82% of TYRVAYA treated patients was sneezing. Other common adverse reactions that were reported in >5% of patients include cough (16%), throat irritation (13%), and instillation-site (nose) irritation (8%).

8 USE IN SPECIFIC POPULATIONS
8.1 Pregnancy
Risk Summary
There are no available data on TYRVAYA use in pregnant women to inform any drug associated risks. In animal reproduction studies, varenicline did not produce malformations at clinically relevant doses.

All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the US general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Data

Animal Data

Pregnant rats and rabbits received varenicline succinate during organogenesis at oral doses up to 15 and 30 mg/kg/day, respectively. While no fetal structural abnormalities occurred in either species, maternal toxicity, characterized by reduced body weight gain, and reduced fetal weights occurred in rabbits at the highest dose (4864 times the MRHD on a mg/m^2 basis).

In a pre- and postnatal development study, pregnant rats received up to 15 mg/kg/day of oral varenicline succinate from organogenesis through lactation. Maternal toxicity, characterized by a decrease in body weight gain, was observed at 15 mg/kg/day (1216 times the MRHD on a mg/m^2 basis). Decreased fertility and increased auditory startle response occurred in offspring at the highest maternal dose of 15 mg/kg/day.

8.2 Lactation

Risk Summary

There are no data on the presence of varenicline in human milk, the effects on the breastfed infant, or the effects on milk production. In animal studies varenicline was present in milk of lactating rats. However, due to species-specific differences in lactation physiology, animal data may not reliably predict drug levels in human milk.

The lack of clinical data during lactation precludes a clear determination of the risk of TYRVAYA to an infant during lactation; however, the developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for TYRVAYA and any potential adverse effects on the breastfed child from TYRVAYA.

8.4 Pediatric Use

Safety and efficacy of TYRVAYA in pediatric patients have not been established.

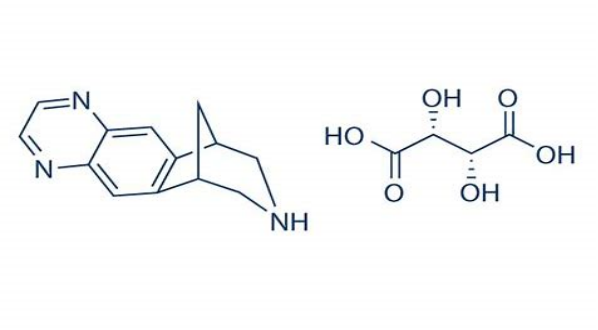
8.5 Geriatric Use

No overall differences in safety or effectiveness have been observed between elderly and younger adult patients.

11 DESCRIPTION

TYRVAYA nasal spray contains varenicline which is a partial nicotinic acetylcholine receptor agonist of α4β2, α4α6β2, α3β4, and α3α5β4 receptors and a full α7 receptor agonist.

Varenicline, as the tartrate salt, is a powder which is a white to off-white to slightly yellow solid whose chemical name is 7,8,9,10-tetrahydro-6,10-methano-6*H*-pyrazino[2,3-h][3]benzazepine, (2*R*,3*R*)-2,3-dihydroxybutanedioate (1:1). It is highly soluble in water. Varenicline tartrate has a molecular weight of 361.35 Daltons and a molecular formula of $C_{13}H_{13}N_3 \cdot C_4H_6O_6$. The chemical structure is:



TYRVAYA (varenicline solution) nasal spray is formulated for intranasal use as a clear 0.6 mg/mL strength solution, at pH 6.4. After priming *[see Dosage and Administration (2.2)]*, each actuation delivers a 0.05 mL spray containing 0.03 mg varenicline free base, equivalent to 0.05 mg of varenicline tartrate. The formulation also contains the following inactive ingredients: sodium phosphate dibasic heptahydrate, monobasic sodium phosphate anhydrous, sodium chloride, sodium hydroxide and/or hydrochloric acid (to adjust pH) and water for injection.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

The efficacy of TYRVAYA in dry eye disease is believed to be the result of varenicline's activity at heteromeric sub-type(s) of the nicotinic acetylcholine (nACh) receptor where its binding produces agonist activity and activates the trigeminal parasympathetic pathway resulting in increased production of basal tear film as a treatment for dry eye disease. Varenicline binds with high affinity and selectivity at human α4β2, α4α6β2, α3β4, α3α5β4 and α7 neuronal nicotinic acetylcholine receptors. The exact mechanism of action is unknown at this time.

12.3 Pharmacokinetics

Absorption/Distribution

Following administration of 0.12 mg (0.06 mg per 50-µL spray in each nostril), a strength of varenicline that is higher than the labeled concentration, varenicline can be detected in plasma by 5 minutes, generally achieves peak concentration within 2 hours, with a mean C_{max} of 0.34 ng/mL, and has an $AUC_{0\text{-}inf}$ of 7.46 h*ng/mL. The systemic exposure ($AUC_{0\text{-}inf}$) following this intranasal dose was approximately 7.5% of the exposure observed following a 1 mg oral dose of varenicline.

Metabolism/Elimination

The mean ± SD elimination half-life of varenicline after intranasal administration is approximately 19 ± 10 hours. Varenicline undergoes minimal metabolism with 92% excreted as unchanged drug in the urine.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

Lifetime carcinogenicity studies were performed in CD-1 mice and Sprague-Dawley rats. There was no evidence of a carcinogenic effect in mice administered varenicline by oral gavage for 2 years at doses up to 20 mg/kg/day (810 times the maximum recommended human dose [MRHD], on a mg/m^2 basis). Rats were administered varenicline (1, 5, and 15 mg/kg/day) by oral gavage for 2 years. In male rats (n = 65 per sex per dose group), incidences of hibernoma

(tumor of the brown fat) were increased at the mid dose (1 tumor, 5 mg/kg/day, 405 times the MRHD on a mg/m^2 basis) and maximum dose (2 tumors, 15 mg/kg/day, 1216 times the MRHD on a mg/m^2 basis). The clinical relevance of this finding to humans has not been established. There was no evidence of carcinogenicity in female rats.

Mutagenesis
Varenicline was not genotoxic, with or without metabolic activation, in the following assays: Ames bacterial mutation assay; mammalian CHO/HGPRT assay; and tests for cytogenetic aberrations *in vivo* in rat bone marrow and *in vitro* in human lymphocytes.

Impairment of Fertility
There was no evidence of impairment of fertility in either male or female Sprague-Dawley rats administered varenicline succinate up to 15 mg/kg/day (1216 times the MRHD on a mg/m^2 basis). Maternal toxicity, characterized by a decrease in body weight gain, was observed at 15 mg/kg/day. A decrease in fertility was noted in the offspring of pregnant rats administered varenicline succinate at an oral dose of 15 mg/kg/day. The decrease in fertility in the offspring of treated female rats was not evident at an oral dose of 3 mg/kg/day (243 times the MRHD, on a mg/m^2 basis).

14 CLINICAL STUDIES
The efficacy of TYRVAYA for the treatment of dry eye disease was supported by two randomized, multi-center, double-masked, vehicle-controlled studies (ONSET-1 and ONSET-2). In the ONSET-1 study, 182 patients were randomized in a 1:1:1:1 ratio to receive one spray in each nostril twice daily of varenicline solution 0.006 mg (N=47), TYRVAYA 0.03 mg (N=48), varenicline solution 0.06 mg (N=44), or vehicle (N=43). In the ONSET-2 study, 758 patients were randomized in a 1:1:1 ratio to receive one spray in each nostril twice daily of TYRVAYA 0.03 mg (N=260), varenicline solution 0.06 mg (N=246), or vehicle (N=252).

The majority of patients were female (74%), the mean (standard deviation [SD]) age was 61 (12.5) years, the mean (SD) baseline anesthetized Schirmer's score was 5.1 mm (2.9), and the mean (SD) baseline eye dryness score (EDS) was 59.3 (21.6. Use of artificial tears was allowed during the studies. Enrollment criteria included minimal signs [i.e., anesthetized Schirmer's test score (range, 0-10 mm) and corneal fluorescein staining (range, 2-14)] and was not limited by baseline EDS (range, 2-100).

Efficacy
Tear film production was measured by anesthetized Schirmer's score assessed using a Schirmer's strip (0-35 mm). The average baseline Schirmer's score was 5.0 mm in the ONSET-1 study and 5.1 mm in the ONSET-2 study. Of the patients treated with TYRVAYA, 52% achieved ≥10 mm increase in Schirmer's score from baseline in the ONSET-1 study and 47% achieved ≥10 mm increase in Schirmer's score from baseline in the ONSET-2 study, compared to 14% and 28% of vehicle-treated patients in the ONSET-1 study and the ONSET-2 study, respectively at Day 28 (see Table 1). Of the patients treated with TYRVAYA, the mean change in Schirmer's score was 11.7 mm and 11.3 mm as compared to 3.2 mm and 6.3 mm in the vehicle treated patients in the ONSET-1 study and ONSET-2 study, respectively at Day 28.

Table 1: Percent of Patients Achieving ≥10 mm Improvement from Baseline in Schirmer's Score in 28-day Studies in Patients with Dry Eye Disease

	ONSET-1		ONSET-2	
	TYRVAYA N=48	**Vehicle N=43**	**TYRVAYA N=260**	**Vehicle N=252**
≥ 10-mm increase in tear production (% of eyes) at Day 28	52%	14%	47%	28%
Proportion Difference (95% CI)	38% (21%, 56%)		20% (11%, 28%)	
p-value versus control	<0.01		<0.01	

Cochran-Mantel-Haenszel (CMH) test controlling for study site, baseline Schirmer's test score (STS), and baseline EDS.
All randomized and treated patients were included in the analysis and missing data were imputed using last-available data.

16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

TYRVAYA (varenicline solution) nasal spray is available in a carton containing two (2) nasal spray amber glass Type I bottles. Each bottle consists of a white nasal pump and blue dust cover, delivering 0.03 mg varenicline per spray (0.05 mL). Each bottle delivers one spray in each nostril twice daily for 15 days.

Two nasal spray bottles in each carton, containing 60 sprays per bottle, equivalent to 30-days' supply with one spray in each nostril twice daily (NDC 73521-030-02).

16.2 Storage and Handling

- Store TYRVAYA nasal spray at 20°C to 25°C (68°F to 77°F). Do not freeze.
- Discard TYRVAYA nasal spray bottle 30 days after opening bottle.

17 PATIENT COUNSELING INFORMATION

- Advise the patient to read the FDA-approved patient labeling (Patient Information and Instructions for Use).

- Instruct patients that TYRVAYA works to increase tear production in the eye after being sprayed in the nose.

- Instruct patients to prime the bottle before using it for the first time by pumping seven (7) sprays into the air away from the face and to re-prime it by pumping 1 spray into the air away from the face if the bottle has not been used in more than five (5) days.

- Instruct patients to wipe the nasal applicator with a clean tissue after each use.

- Instruct patients to not shake or freeze the bottle.

Manufactured for: Oyster Point Pharma, Inc, 202 Carnegie Center, Suite 109, Princeton, NJ 08540

TYRVAYA™ and/or the use of TYRVAYA™ in a method may be covered by one or more patents or patent applications, available at www.oysterpointrx.com/patent-notices.

Issued: Oct 2021

Patient Information
TYRVAYA™ (Teer-vye-ah)
(varenicline solution)
nasal spray, for intranasal use

What is TYRVAYA?

TYRVAYA is a prescription nasal spray used to treat the signs and symptoms of dry eye disease.

Before you use TYRVAYA, tell your healthcare provider about all of your medical conditions, including if you:

- are pregnant or plan to become pregnant. It is not known if TYRVAYA will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if TYRVAYA passes into your breast milk. You and your healthcare provider should decide if you will use TYRVAYA if you plan to breastfeed.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I use TYRVAYA?

- See the Instructions for Use at the end of this Patient Information leaflet for information about the right way to use TYRVAYA.
- TYRVAYA increases tear production in the eye after being sprayed in the nose.
- Use TYRVAYA exactly as your healthcare provider tells you to use it.
- Do not shake the bottles.
- Spray TYRVAYA 1 time in each nostril, 2 times daily (about 12 hours apart).
- A 1-month supply of TYRVAYA consists of 2 nasal spray bottles. Finish 1 bottle before opening the second. TYRVAYA comes in glass bottles with a white nasal pump and blue dust cover.
- If you miss a dose of TYRVAYA, skip that dose and take your next dose at your regular scheduled time. Do not take an extra dose to make up for a missed dose.

What are the possible side effects of TYRVAYA?

The most common side effects of TYRVAYA include sneezing, cough, and throat and nose irritation.

These are not the only possible side effects of TYRVAYA. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store TYRVAYA?

- Store TYRVAYA at room temperature between 68°F to 77°F (20°C to 25°C).
- Do not freeze.
- Throw away (discard) TYRVAYA nasal spray bottle 30 days after first use.

Keep TYRVAYA and all medicines out of the reach of children.

General information about the safe and effective use of TYRVAYA.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use TYRVAYA for a condition for which it was not prescribed. Do not give TYRVAYA to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about TYRVAYA that is written for health professionals.

What are the ingredients in TYRVAYA?

Active ingredient: varenicline tartrate

Inactive ingredients: sodium phosphate dibasic heptahydrate, monobasic sodium phosphate, anhydrous, sodium chloride, sodium hydroxide and/or hydrochloric acid (to adjust pH) and water for injection.

Manufactured for: Oyster Point Pharma, Inc., 202 Carnegie Center, Suite 109, Princeton, NJ 08540

Instructions for Use
TYRVAYA™ (Teer-vye-ah)
(varenicline solution)
nasal spray, for intranasal use

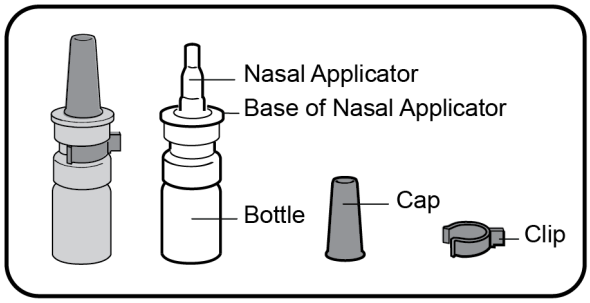
Read this Instructions for Use before you start using TYRVAYA and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

Important information you need to know before using TYRVAYA:

- **TYRVAYA is for use in the nose.**
- **Do not shake the bottles.**

- The TYRVAYA carton contains enough medicine for 30 days.
  - Each carton has 2 glass nasal spray bottles.
  - Each nasal spray bottle has enough medicine for 15 days of treatment.
  - **Do not** open the second nasal spray bottle until you have used the entire first bottle.

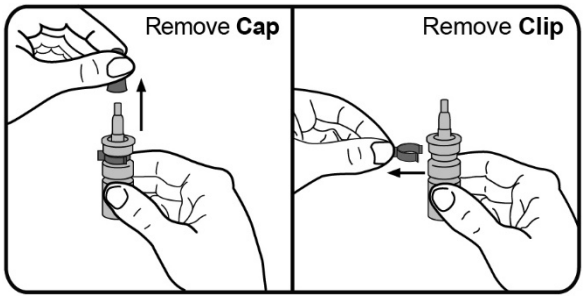
Parts of your TYRVAYA nasal spray:



Steps for priming TYRVAYA before first Use

Step 1. Remove the cap and the clip.

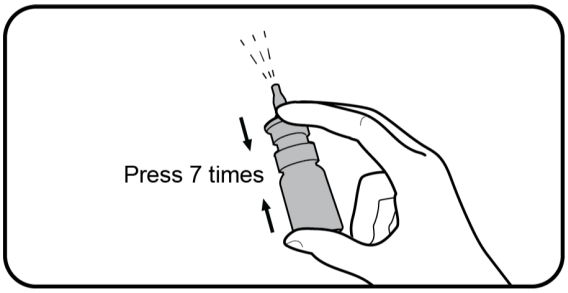
Do not throw away the cap or the clip. The cap and the clip will be placed back on to the nasal applicator after each use.



Step 2. Hold the nasal spray bottle upright and away from your face. Place 1 finger on each side of the base of the nasal applicator and place your thumb underneath the bottle.

Step 3. Prime the nasal spray bottle by pressing and releasing the nasal applicator 7 times with your thumb and fingers. You may not see a spray released each time you press and release the nasal applicator. Spray away from yourself and others.

TYRVAYA is now primed for use.



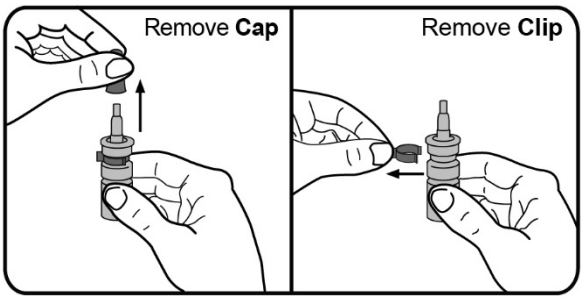
- **Reprime**: If you do not use TYRVAYA for more than **5 days**, you will need to reprime the nasal spray bottle with **1 spray** before you start using it. To reprime, hold the nasal spray bottle upright and away from your face and press and release the nasal spray applicator **1 time**.
- **Avoid priming the nasal spray bottle more than needed**: Priming the nasal spray bottle more than needed will reduce the amount of medicine in the nasal spray bottle.

Steps for using TYRVAYA nasal spray after priming

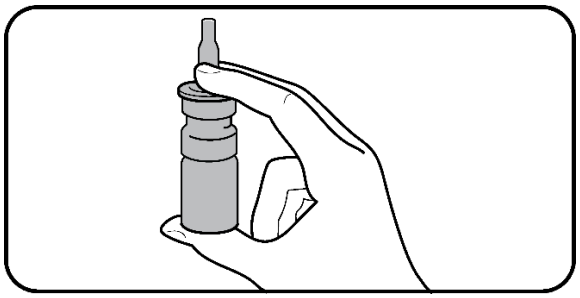
Step 1. Blow your nose to clear your nostrils, if needed.

Step 2. Remove the cap and clip.

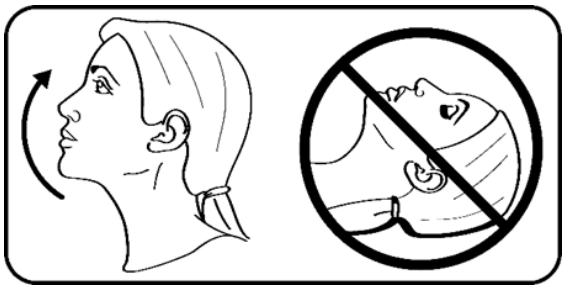
Do not throw away the cap or the clip. The cap and the clip will be placed back on to the nasal applicator after each use.



Step 3. Hold the nasal spray bottle upright. Place 1 finger on each side of the base of the nasal applicator and your thumb underneath the bottle.



Step 4. Tilt your head back slightly without lying down.

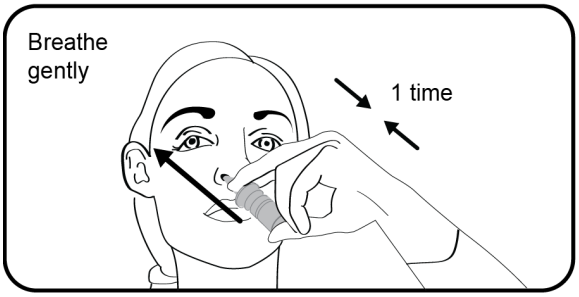


Step 5. Insert the nasal applicator into the left or right nostril. Tilt the nasal applicator and point the tip of the nasal applicator towards the top of the ear on the same side as your nostril.

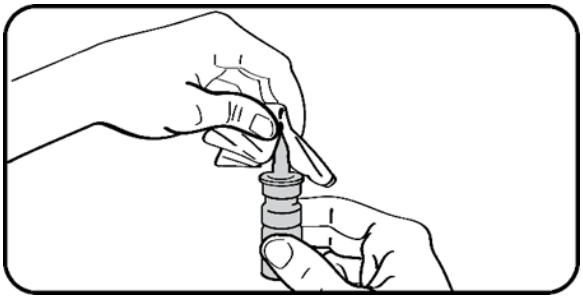
Do not press the tip of the nasal applicator against the wall of the inside of your nose. Leave a space between the tip of the nasal applicator and the wall of the inside of your nose.

Step 6. Place your tongue to the roof of your mouth and breathe gently while pressing and releasing the nasal applicator **1-time** to release a spray into your nostril.

Repeat Steps 5 and 6 to deliver a second spray in the other nostril.

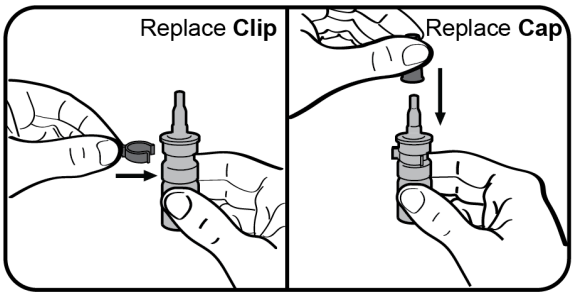


Step 7. Wipe the nasal applicator with a clean tissue.



Step 8. Replace the clip and the cap.

Repeat Steps 1 to 8 each time you use TYRVAYA.



This Instructions for Use has been approved by the U.S. Food and Drug Administration.
TYRVAYA™ is a trademark of Oyster Point Pharma, Inc.
TYRVAYA™ and/or the use of TYRVAYA™ in a method may be covered by one or more patents or patent applications, available at www.oysterpointrx.com/patent-notices.
Manufactured for: Oyster Point Pharma, Inc., 202 Carnegie Center, Suite 109, Princeton, NJ 08540

Issued: 10/2021

Excerpts from the Laws Governing Optometry

§ 54.1-3222. TPA certification; certification for treatment of diseases or abnormal conditions with therapeutic pharmaceutical agents.

A. The Board shall certify an optometrist to prescribe for and treat diseases or abnormal conditions of the human eye and its adnexa with therapeutic pharmaceutical agents (TPAs), if the optometrist files a written application, accompanied by the fee required by the Board and satisfactory proof that the applicant:

1. Is licensed by the Board as an optometrist and certified to administer diagnostic pharmaceutical agents pursuant to Article 4 (§ 54.1-3220 et seq.);

2. Has satisfactorily completed such didactic and clinical training programs for the treatment of diseases and abnormal conditions of the eye and its adnexa as are determined, after consultation with a school or college of optometry and a school of medicine, to be reasonable and necessary by the Board to ensure an appropriate standard of medical care for patients; and

3. Passes such examinations as are determined to be reasonable and necessary by the Board to ensure an appropriate standard of medical care for patients.

B. TPA certification shall enable an optometrist to prescribe and administer, within his scope of practice, Schedule II controlled substances consisting of hydrocodone in combination with acetaminophen and Schedules III through VI controlled substances and devices as set forth in the Drug Control Act (§ 54.1-3400 et seq.) to treat diseases and abnormal conditions of the human eye and its adnexa as determined by the Board, within the following conditions:

1. Treatment with oral therapeutic pharmaceutical agents shall be limited to (i) analgesics included on Schedule II controlled substances as defined in § 54.1-3448 of the Drug Control Act (§ 54.1-3400 et seq.) consisting of hydrocodone in combination with acetaminophen, and analgesics included on Schedules III through VI, as defined in §§ 54.1-3450 and 54.1-3455 of the Drug Control Act, which are appropriate to alleviate ocular pain and (ii) other Schedule VI controlled substances as defined in § 54.1-3455 of the Drug Control Act appropriate to treat diseases and abnormal conditions of the human eye and its adnexa.

2. Therapeutic pharmaceutical agents shall include topically applied Schedule VI drugs as defined in § 54.1-3455 of the Drug Control Act (§ 54.1-3400 et seq.).

3. Administration of therapeutic pharmaceutical agents by injection shall be limited to the treatment of chalazia by means of injection of a steroid included in Schedule VI controlled substances as set forth in § 54.1-3455 of the Drug Control Act (§ 54.1-3400 et seq.). A TPA-certified optometrist shall provide written evidence to the Board that he has completed a didactic and clinical training course provided by an accredited school or college of optometry that includes training in administration of TPAs by injection prior to administering TPAs by injection pursuant to this subdivision.

4. Treatment of angle closure glaucoma shall be limited to initiation of immediate emergency care.

5. Treatment of infantile or congenital glaucoma shall be prohibited.

6. Treatment through surgery or other invasive modalities shall not be permitted, except as provided in subdivision 3 or for treatment of emergency cases of anaphylactic shock with intramuscular epinephrine.

7. Entities permitted or licensed by the Board of Pharmacy to distribute or dispense drugs, including, but not limited to, wholesale distributors and pharmacists, shall be authorized to supply TPA-certified optometrists with those therapeutic pharmaceutical agents specified by the Board on the TPA-Formulary.

1996, cc. 152, 158; 2004, c. 744; 2015, c. 355; 2018, c. 280.

§ 54.1-3223. Regulations relating to instruction and training, examination, and therapeutic pharmaceutical agents.

A. The Board shall promulgate such regulations governing the treatment of diseases and abnormal conditions of the human eye and its adnexa with therapeutic pharmaceutical agents by TPA-certified optometrists as are reasonable and necessary to ensure an appropriate standard of medical care for patients, including, but not limited to, determinations of the diseases and abnormal conditions of the human eye and its adnexa that may be treated by TPA-certified optometrists, treatment guidelines, and the drugs specified on the TPA-Formulary.

In establishing standards of instruction and training, the Board shall consult with a school or college of optometry and a school or college of medicine and shall set a minimum number of hours of clinical training to be supervised by an ophthalmologist. The didactic and clinical training programs may include, but need not be limited to, programs offered or designed either by schools of medicine or schools or colleges of optometry or both or some combination thereof.

The Board may prepare, administer, and grade appropriate examinations for the certification of optometrists to administer therapeutic pharmaceutical agents or may contract with a school of medicine, school or college of optometry, or other institution or entity to develop, administer, and grade the examinations.

In order to maintain a current and appropriate list of therapeutic pharmaceuticals on the TPA-Formulary, current and appropriate treatment guidelines, and current and appropriate determinations of diseases and abnormal conditions of the eye and its adnexa that may be treated by TPA-certified optometrists, the Board may, from time to time, amend such regulations. Such regulations shall be exempt from the requirements of the Administrative Process Act (§ 2.2-4000 et seq.), except to any extent that they may be specifically made subject to §§ 2.2-4024, 2.2-4030, and 2.2-4031; the Board's regulations shall, however, comply with § 2.2-4103 of the Virginia Register Act (§ 2.2-4100 et seq.). The Board shall, however, conduct a public hearing prior to making amendments to the TPA-Formulary, the treatment guidelines or the

determinations of diseases and abnormal conditions of the eye and its adnexa that may be treated by TPA-certified optometrists. Thirty days prior to conducting such hearing, the Board shall give written notice by mail of the date, time, and place of the hearing to all currently TPA-certified optometrists and any other persons requesting to be notified of the hearings and publish notice of its intention to amend the list in the Virginia Register of Regulations. During the public hearing, interested parties shall be given reasonable opportunity to be heard and present information prior to final adoption of any TPA-Formulary amendments. Proposed and final amendments of the list shall also be published, pursuant to § 2.2-4031, in the Virginia Register of Regulations. Final amendments to the TPA-Formulary shall become effective upon filing with the Registrar of Regulations. The TPA-Formulary shall be the inclusive list of the therapeutic pharmaceutical agents that a TPA-certified optometrist may prescribe.

B. To assist in the specification of the TPA-Formulary, there shall be a seven-member TPA-Formulary Committee, as follows: three Virginia TPA-certified optometrists to be appointed by the Board of Optometry, one pharmacist appointed by the Board of Pharmacy from among its licensees, two ophthalmologists appointed by the Board of Medicine from among its licensees, and the chairman who shall be appointed by the Board of Optometry from among its members. The ophthalmologists appointed by the Board of Medicine shall have demonstrated, through professional experience, knowledge of the optometric profession. In the event the Board of Pharmacy or the Board of Medicine fails to make appointments to the TPA-Formulary Committee within 30 days following the Board of Optometry's requesting such appointments, or within 30 days following any subsequent vacancy, the Board of Optometry shall appoint such members.

The TPA-Formulary Committee shall recommend to the Board those therapeutic pharmaceutical agents to be included on the TPA-Formulary for the treatment of diseases and abnormal conditions of the eye and its adnexa by TPA-certified optometrists.

(1996, cc. 152, 158; 2004, c. 744.)

Excerpts from the Regulations of the Virginia Board of Optometry

18VAC105-20-46. Treatment guidelines for TPA-certified optometrists.

A. TPA-certified optometrists may treat diseases and abnormal conditions of the human eye and its adnexa that may be treated with medically appropriate pharmaceutical agents as referenced in 18VAC105-20-47.

B. In addition, the following may be treated:

1. Glaucoma (excluding the treatment of congenital and infantile glaucoma). Treatment of angle closure shall follow the definition and protocol prescribed in subsection C of this section.

2. Ocular-related post-operative care in cooperation with patient's surgeon.

3. Ocular trauma to the above tissues as in subsection A of this section.

4. Uveitis.

5. Anaphylactic shock (limited to the administration of intramuscular epinephrine).

C. The definition and protocol for treatment of angle closure glaucoma shall be as follows:

1. As used in this chapter, angle closure glaucoma shall mean a closed angle in the involved eye with significantly increased intraocular pressure, and corneal microcystic edema;

2. Treatment shall be limited to the initiation of immediate emergency care with appropriate pharmaceutical agents as prescribed by this chapter;

3. Once the diagnosis of angle closure glaucoma has been established by the optometrist, the ophthalmologist to whom the patient is to be referred should be contacted immediately;

4. If there are no medical contraindications, an oral osmotic agent may be administered as well as an oral carbonic anhydrase inhibitor and any other medically accepted, Schedule III, IV or VI, oral antiglaucomic agent as may become available; and

5. Proper topical medications as appropriate may also be administered by the optometrist.

D. An oral Schedule VI immunosuppressive agent shall only be used when (i) the condition fails to appropriately respond to any other treatment regimen; (ii) such agent is prescribed in consultation with a physician; and (iii) treatment with such agent includes monitoring of systemic effects.

18VAC105-20-47. Therapeutic pharmaceutical agents.

A. A TPA-certified optometrist, acting within the scope of his practice, may procure, administer, and prescribe medically appropriate therapeutic pharmaceutical agents (or any therapeutically appropriate combination thereof) to treat diseases and abnormal conditions of the human eye and its adnexa within the following categories:

1. Oral analgesics - Schedule II controlled substances consisting of hydrocodone in combination with acetaminophen and Schedules III, IV, and VI narcotic and nonnarcotic agents.

2. Topically administered Schedule VI agents:

a. Alpha-adrenergic blocking agents;

b. Alpha-adrenergic agonists;

c. Anesthetic (including esters and amides);

d. Anti-allergy (including antihistamines and mast cell stabilizers);

e. Anti-fungal;

f. Anti-glaucoma (including carbonic anhydrase inhibitors and hyperosmotics);

g. Anti-infective (including antibiotics and antivirals);

h. Anti-inflammatory;

i Cycloplegics and mydriatics;

j. Decongestants; and

k. Immunosuppressive agents.

3. Orally administered Schedule VI agents:

a. Aminocaproic acids (including antifibrinolytic agents);

b. Anti-allergy (including antihistamines and leukotriene inhibitors);

c. Anti-fungal;

d. Anti-glaucoma (including carbonic anhydrase inhibitors and hyperosmotics);

e. Anti-infective (including antibiotics and antivirals);

f. Anti-inflammatory (including steroidal and nonsteroidal);

g. Decongestants; and

h. Immunosuppressive agents.

B. Schedules I, II, and V drugs are excluded from the list of therapeutic pharmaceutical agents with the exception of controlled substances in Schedule II consisting of hydrocodone in combination with acetaminophen and gabapentin in Schedule V.

C. Over-the-counter topical and oral medications for the treatment of the eye and its adnexa may be procured for administration, administered, prescribed, or dispensed.