**BOARD OF OPTOMETRY**
**VIRTUAL TPA FORMULARY COMMITTEE**
**MEETING MINUTES**
**September 14, 2020**

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| **TIME AND PLACE:** | A virtual meeting via Webex of the TPA Formulary Committee, (Committee) meeting was called to order at 1:00 p.m. |
| **PRESIDING OFFICER:** | Fred Goldberg, O.D. (Virtual Participation) |
| **MEMBERS PARTICIPATING ONSITE:** | Steven Linas, O.D. |
| **MEMBERS PARTICIPATING VIRTUALLY:** | Michael Keverline, M.D.<br>Nicole Langelier, M.D.<br>Cheryl Nelson, Pharmacist<br>Jonathan Noble, O.D.<br>Lisa Wallace-Davis, O.D. |
| **OTHERS PRESENT VIRTUALLY:** | Mark Hickman, Virginia Society of Eye Physicians and Surgeons<br>Christina Markus, King & Spalding<br>Caitlyn Ozier, King & Spalding<br>David Jacobs, M.D. Medical Director, Osmotica |
| **STAFF PARTICIPATING ONSITE:** | Leslie L. Knachel, Executive Director<br>Elaine Yeatts, Senior Policy Analyst<br>Amy Davis, Executive Assistant<br>Celia Wilson, Operations Administrative Assistant<br>Me-Lien Chung, Discipline Case Specialist |
| **STAFF PARTICIPATING VIRTUALLY:** | Kelli Moss, Deputy Executive Director |
| **ORDERING OF AGENDA:** | No changes or additions were made to the agenda. |
| **PUBLIC COMMENT:** | Ms. Knachel read the written comment submitted by Commonwealth Eye Care Associates in support of optometrists being able to prescribe supporting approval of the oxymetazoline hydrochloride. (See Attachment A)<br><br>Christina Markus, regulatory lawyer from King & Spalding presented oral comment asking the TPA-Formulary Committee to recommend to the Board of Optometry a regulatory amendment that will allow the Board to agree that UPNEEQ is legally appropriate for optometrists to prescribe to their patients. (See Attachment B) |
| **DISCUSSION ITEMS:** | Ms. Knachel reviewed the information from the minutes of the July 17, 2020, Board of Optometry meeting which voted to convene the TPA-Formulary Committee to review 18VAC-105-20-47(A)(2) of the Regulations of the Virginia Board of Optometry, Topically Administered Schedule VI Agents and make recommendations to the Board at its next meeting scheduled for October 16, 2020.<br><br>The Board discussed the addition of alpha-adrenergic agonists to the TPA-Formulary. |

Dr. Wallace-Davis moved to add Alpha-adrenergic agonists to the regulations as item (b) of 18VAC-105-20-47(A)(2). The motion was properly seconded by Dr. Noble.

A roll call vote was taken by Ms. Knachel. The motion carried with an unanimous aye vote.

**NEXT STEPS:** Dr. Goldberg reviewed the next steps required Pursuant to §54.1-3223 of the *Code of Virginia*.

**ADJOURNMENT:** The meeting adjourned at 1:34 p.m.

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Fred Goldberg, O.D..
Committee Chair

Leslie L. Knachel, M.P.H
Executive Director

_____ _____

Date

Date

Attachment A

# Commonwealth Eye Care Associates


**Dr. Andrew J. Michael, MD**
*Ophthalmic Consultation and Co-Management*
*Glaucoma Consultation & Surger*
*Cataract Surgery*

**Dr. Shawn H. Hobbs, OD**
*Comprehensive Consultation and Co-Management*
*Treatment of Eye Diseases*
*Pre and Post Surgical Care*

**Dr. Joseph D Iuorno, MD**
*Ophthalmic Consultation and Co-Management*
*Cornea Consultation & Surgery*
*Refractive Consultation & Surger*

**Dr. Tami A. Flowers, MD**
*Ophthalmic Consultation and Co-Management*
*Cataract Surgery*
*External Disease*

**Dr. Meredith L. Diehl, MD**
*Ophthalmic Consultation and Co-Management*
*Ophthalmic Neurological Consultation*

**Dr. Jonathan R. Noble, OD**
*Comprehensive Consultation and Co-Management*
*Treatment of Eye Diseases*
*Pre and Post Surgical Care*

**Dr. Drew D. Munro, MD**
*Ophthalmic Consultation and Co-Management*
*Oculoplastic Consultation & Surgery*
*Orbital & Reconstructive Surgery*

**Dr. Matthew T. Young, MD**
*Ophthalmic Consultation and Co-Management*
*Glaucoma Consultation & Surger*
*Cataract Surgery*

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Virginia Board of Optometry TPA
Committee

September 11, 2020

RE: 0.1% Oxymetazoline HCL solution (Trade name: Upneeq)
Public Comment

Dear Madams and Sirs:
Thank you for soliciting written public comment in anticipation of your Committee's consideration related to this novel formulation of oxymetazoline. Our ophthalmic practice in Central Virginia has specialized in referral care of the full range of ocular pathology for the past 20 years. We receive referrals from over 120 actively practicing Doctors of Optometry, as well as other ophthalmologists and medical practitioners in many disciplines, who see patients in our region and beyond. As a result, we are well-qualified to comment on what is within the reasonable scope of knowledge and practice of optometrists in the Commonwealth of Virginia.

We strongly support approving this formulation of oxymetazoline (Upneeq) for prescription use by Doctors of Optometry. This medication, available in other strengths and formulations, for other indications, is already available over the counter, without prescription, and is often recommended to patients by optometrists and other doctors. This medication has an excellent safety profile. It is well within the purview of optometry and already within their scope of practice to be familiar with this medication. Patients will benefit from their optometrist having the ability to prescribe this medication when indicated. We are fully in favor of your approving this medication for prescription use and management of indicated conditions by Doctors of Optometry in the Commonwealth of Virginia.

Please contact our practice directly if you have questions or if we can be of further assistance.

Respectfully submitted,

Doctors Andrew J. Michael, MD and Joseph D. Iuorno, MD
Commonwealth Eye Care Associates, PC

**Attachment B**

My name is Chris Markus, and I am a regulatory lawyer with the law firm King & Spalding. I am here today representing Osmotica Pharmaceuticals and its affiliated company RVL Pharmaceuticals.
In July 2020, the companies received FDA approval of a new drug product bearing the brand name UPNEEQ™ and the generic name oxymetazoline hydrochloride solution, 0.1%. This product is a locally-acting, topical eyedrop that FDA approved for the treatment of acquired blepharoptosis – also called ptosis or droopy eyelid – in adults. The FDA approval letter and product prescribing information have been included in your briefing materials for today. Essentially, UPNEEQ interacts with the Mueller muscle in the eyelid, and causes the lid muscle to contract and the eyelid to raise – opening the field of vision for affected patients. UPNEEQ is approved for administration once each day to the affected eye or eyes. Before the approval of this product, the primary treatment available for acquired blepharoptosis was surgery.

On the line with me today is David Jacobs, M.D., who served as the Medical Director for Osmotica and RVL Pharmaceuticals during the time the pivotal clinical trials were conducted to demonstrate the safety and effectiveness of UPNEEQ. These trials supported FDA's approval, and Dr. Jacobs can address any questions that the TPA-Formulary Committee may have concerning UPNEEQ or its safety or efficacy profile in patients.

We appreciate your attention today to this first-in-class drug approval to treat acquired blepharoptosis in adults.

We recently asked the Virginia Board of Optometry to affirm that UPNEEQ is within the scope of prescribing authority for qualified Virginia optometrists. The governing statute for the practice of optometry (Va. Code § 54.1-3222.B.) states that: "TPA certification shall enable an optometrist to prescribe and administer … Schedules III through VI controlled substances … to treat diseases and abnormal conditions of the human eye and its adnexa as determined by the Board, within the following conditions: …2. Therapeutic pharmaceutical agents shall include topically applied Schedule VI drugs as defined in § 54.1-3455 of the Drug Control Act…."

However, the regulation that you are reviewing today establishes limitations – via the exclusive enumeration of covered categories – that does not appear currently broad enough to recognize UPNEEQ. Some of the categories are defined by mechanism of action; for example, one authorizes optometrists' prescription of "alpha adrenergic antagonists" – however, UPNEEQ is an alpha adrenergic agonist. Other categories are defined by therapeutic purpose; however, UPNEEQ does not fit appear to fit within any of the listed therapeutic categories. We respectfully request today that the Committee develop a recommendation for how the Board of Optometry can amend its regulation and facilitate patient access through optometrist prescribing of UPNEEQ.

We would like to share with the Committee that we have reviewed optometrist prescribing laws covering the United States. In the majority of states, the legal provisions do not impose exclusive limitations affecting this product. We have had to seek clarification in a handful of jurisdictions (Connecticut, the District of Columbia, Illinois, Kansas, New Hampshire, Oregon, and Virginia), but those respective Boards of Optometry or their staffs to date have generally confirmed that UPNEEQ is within the authorized scope of optometrist prescribing authority. We are awaiting feedback from Connecticut, Illinois, and Virginia.

Again, we ask the TPA-Formulary Committee to recommend to the Board of Optometry a regulatory amendment that will allow the Board to agree that UPNEEQ is legally appropriate for optometrists to prescribe to their patients. This could be accomplished by a product-specific or a general regulatory clarification.

Thank you.

**Christina M. Markus**

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