

Lecture Title: Presbyopia Pharmaceuticals on the Horizon

Length: 1 hour

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Course Description:

This course examines the evolving landscape of pharmaceutical therapies for presbyopia, with a focus on emerging agents beyond pilocarpine. Attendees will explore novel mechanisms of action, investigational drugs in development, and the potential impact these therapies may have on presbyopia management. Emphasis will be placed on clinical trial data, patient selection considerations, and how these therapies may integrate into future optometric practice.

Course Objectives:

1. Review investigational pharmaceutical agents currently being studied for presbyopia management.
2. Understand the different mechanisms of action targeted by emerging presbyopia therapies.
3. Discuss safety profiles, efficacy data, and limitations of drugs in clinical development.
4. Anticipate how new pharmaceutical options may influence patient expectations and presbyopia care pathways.
5. Recognize areas of ongoing research and potential future directions in presbyopia drug development.

Course Outline:

1. Presbyopia Overview

- a. Pathophysiology of presbyopia
 - i. Loss of lens elasticity and accommodative amplitude
 - ii. Role of:
 1. ciliary muscle
 2. lens proteins
 3. oxidative stress
- b. Epidemiology and prevalence in patients over 40
- c. Psychological and lifestyle impact of presbyopia

2. Current Standard Approaches

- a. Optical strategies
 - i. Spectacles
 - ii. contact lenses
 - iii. multifocal options
- b. Surgical approaches
 - i. corneal inlays
 - ii. LASIK/PRK enhancements
 - iii. presbyopia-correcting IOLs
- c. FDA-approved pharmacologic option: pilocarpine 1.25%
 - i. Brief review of mechanism (miotic → pinhole effect)
 - ii. Limitations and patient considerations

3. Pilocarpine Overview

- a. Historical context:
 - i. Glaucoma treatment, Acute angle-closure
 - ii. Role in diagnosis of other conditions
 - 1. Differentiating conditions
 - a. Aidie's Tonic Pupil
 - b. Horner's Syndrome
 - iii. FDA approval for presbyopia treatment
 - 1. Overview of 4%, 1.25% and 0.4% formulations
- b. Mechanism of action
 - i. Cholinergic agonist stimulating ciliary muscle contraction

4. Clinical Studies and Current Evidence

- a. Key Clinical Trials of Pilocarpine
 - i. Overview of pivotal studies and clinical endpoints
 - 1. FDA-approved studies for presbyopia treatment
 - a. Pilocarpine 1.25%
 - b. Pilocarpine 0.4%
 - ii. Patient selection criteria and demographics
 - iii. Key Inclusion Criteria
 - iv. Key Exclusion Criteria

- v. Duration of action, dosing frequency
- vi. Comparative data

5. Clinical Application & Patient Counseling

- a. Anticipating how new therapies may integrate into practice
 - i. Ideal patient profiles for future presbyopia drops
 - ii. Contraindications and risk considerations
- b. Counseling patients on realistic expectations
 - i. Duration of action
 - ii. Night vision concerns
 - iii. Neuroadaptation
- c. Balancing pharmacologic therapy with optical and surgical options

6. Emerging Pharmaceutical Mechanisms

- a. Miotics and Combination Drops
 - i. Carbachol-based agents
 - ii. Aceclidine + brimonidine formulations
 - iii. Comparative pharmacodynamics to pilocarpine
- b. Lens-Softening Agents
 - i. Lipoic acid choline ester (UNR844) and others in development
 - ii. Mechanism: disulfide bond reduction to restore lens flexibility
 - iii. Current status of trials and challenges in efficacy
- c. Ciliary Muscle Modulators
 - i. Agents targeting accommodation physiology
 - ii. Theoretical basis and early-stage development
- d. Novel Delivery Methods
 - i. Nasal sprays
 - ii. Sustained-release vehicles
 - iii. Combination therapies

7. Future Innovations

- a. Pipeline update: agents in late-stage development
- b. Longer-acting formulations and combination therapies
- c. Expanding indications beyond presbyopia

- i. (e.g., accommodative dysfunction)
- d. Patient-centered care:
 - i. integrating lifestyle
 - ii. safety
 - iii. access considerations
- e. Cost, accessibility, and potential insurance issues

8. Case Examples, Questions, & Discussion

- a. Case 1: Emmetropic patient with early presbyopia considering drops
 - i. Discussion / Questions
- b. Case 2: Post-refractive surgery patient exploring pharmacologic options
 - i. Discussion / Questions
- c. Case 3: Patient dissatisfied with optical correction seeking non-surgical solutions
 - i. Discussion / Questions