

Aceclidine ophthalmic solution (VIZZ) National Drug Monograph October 2025

VA Pharmacy Benefits Management Services and VA National Formulary Committee

The purpose of VA PBM Services drug monographs is to provide a focused drug review for making formulary decisions. Updates will be made if new clinical data warrant additional formulary discussion. The Product Information or other resources should be consulted for detailed and most current drug information.

FDA Approval Information¹

Description/Mechanism of Action

- Aceclidine is a cholinergic muscarinic agonist

Indication(s) Under Review in This Document

- Aceclidine is indicated for the treatment of presbyopia

Dosage Form(s) Under Review

- Ophthalmic solution: aceclidine 1.44% in a single-dose vial

Clinical Evidence Summary

Efficacy Considerations ¹

- The efficacy of aceclidine, supporting its FDA approval, was evaluated from industry-sponsored studies, including two phase 3 randomized, multicenter, double-masked, active/vehicle-controlled safety and efficacy studies (CLARITY-1 [NCT05656027] and CLARITY-2 [NCT06045299])
- 466 participants aged 45-75 years old with presbyopia were randomized
- Participants had a refractive range from -4.00 to +1.00 D sphere, with astigmatism up to 2.00 D, and a spherical equivalent no more myopic than -4.00 D (See inclusion/exclusion criteria for CLARITY-1 below)
- Participants were instructed to instill 2 drops of aceclidine (or control) in each eye once daily, one drop in each eye followed by a second drop in each eye two minutes later for 42 days
- Ophthalmic efficacy assessments were conducted on Day 1, Day 15, and Day 28 of the study at various timepoints through 10 hours post dose
- The primary outcome measure was the proportion of participants gaining 3 lines or more in high contrast, distance corrected, near visual acuity (DCNVA) at 40 cm, without loss of 1 line or more (≥ 5 letters) of distance corrected, distance visual acuity (DCDVA) at 4 meters on Day 1, at 3 hours
- Aceclidine produced statistically significantly greater DCNVA without loss of DCDVA on Day 1 at 3 hours (Table 1)

CLARITY-1 Criteria

Inclusion Criteria:³

1. Be able and willing to provide written informed consent and sign a Health Information Portability and Accountability Act (HIPAA) form prior to any study procedure being performed;
2. Be able and willing to follow all instructions and attend all study visits;
3. Be 45-75 years of age of either sex and any race or ethnicity at Visit 1;
4. Have +1.00 to -4.00 diopter (D) of sphere calculated in minus cylinder (so that spherical equivalent (SE) results in myopia no more severe than -4.00 D MRSE) in both eyes determined by manifest refraction documented at Visit 1;
5. Have ≤ 2.00 D of cylinder (minus cylinder) in both eyes determined by manifest refraction documented at Visit 1;
6. Be presbyopic as determined at Visit 1

Exclusion Criteria:³

Subjects must not:

1. Be a female of childbearing potential who is currently pregnant, nursing, or planning a pregnancy;
2. Have known contraindications or sensitivity to the use of any of the study medications or their components;
3. Have an active ocular infection at Visit 1 or at Visit 2 (bacterial, viral, or fungal), positive history of an ocular herpetic infection, preauricular lymphadenopathy, or ongoing, active ocular inflammation in either eye;
4. Have moderate or severe dry eye defined as total central corneal fluorescein staining in either eye at Visit 1;
5. Have clinically significant abnormal lens findings including early lens changes in either eye during dilated slit-lamp biomicroscopy and fundus exam documented within 3 months of Visit 1 or at Visit 1;

Table 1. Primary Efficacy Endpoint Day 1 at 3 hours post dose

	CLARITY-1			CLARITY-2		
	Aceclidine N=157	Brimonidine N=156	p-value	Aceclidine N=77	Vehicle N=76	p-value
Proportion of participants gaining 3-lines or more in DCNVA at 40cm, without losing 1 line or more (≥ 5 letters) of DCDVA at 4m on Day 1, at 3 hours	65%	12%	P<0.01	71%	8%	P<0.01

DCNVA: distance corrected, near visual acuity, m: meters

Safety Considerations¹

Contraindications:

- None

Other warnings and precautions¹

- Blurred vision
- Risk of retinal tear/detachment
- Iritis
- Hypersensitivity
- Potential for eye injury and contamination
- Use with contact lenses – contact lenses should be removed prior to aceclidine administration

Adverse Reactions¹ (CLARITY-1, CLARITY-2)

The adverse reactions reported in the clinical trials were instillation site irritation (20%), dim vision (16%), headache (13%), conjunctival hyperemia (8%), and ocular hyperemia (7%)

Other Therapeutic Options

Table 2.

Drug	Formulary status	Clinical Guidance/ Indication	Comments
Aceclidine (Vizz)	NF/TBD	Presbyopia	Instill 1 drop in each eye, wait 2 minutes and instill a second drop in each eye once daily from the same single-dose vial.
Pilocarpine 1.25% (Vuity)	NF	Presbyopia	Administered 1 drop in each eye daily with an option for a second dose 3-6 hours later if needed. 2.5ml and 5ml bottles
Pilocarpine 0.4% (Qlosi)	NF	Presbyopia	Can be used daily or as needed, 1 drop in each eye followed by an additional drop 2-3 hours later if needed. Single use vials

Projected Place in Therapy

- Presbyopia is the gradual loss of your eyes' ability to focus on nearby objects, typically noticeable in your early to middle forties and worsening until around age 65. This condition occurs as the eye's natural lens becomes less flexible with aging, making it difficult to see close-up objects clearly. It is a common refractive error that affects many middle-aged and older adults. Treatment options may include reading glasses, contact lenses, refractive surgery, lens implants and eye drops
- There are three eye drops FDA approved for the treatment of presbyopia. Two are pilocarpine products and one is aceclidine, all are cholinergic agonists. No head-to-head studies among the approved available agents have been conducted.
- CLARITY-1 and CLARITY-2 showed that aceclidine produced statistically significantly greater DCNVA without loss of DCDVA on Day 1 at 3 hours compared to brimonidine or vehicle (control)
- Aceclidine is the third FDA approved agent for the treatment of presbyopia, that adds to the list of available agents used to treat presbyopia

References

1. VIZZ (aceclidine ophthalmic solution) [prescribing information]. Lenz Therapeutics, Inc. Solana Beach, CA 2025.
2. A Multi-Center, Double-Masked Phase 3 Evaluation of the Safety and Efficacy of LNZ101 for the Treatment of Presbyopia. Clinicaltrials.gov. Accessed August 22, 2025.
3. A Multi-Center, Randomized, Double-Masked, Placebo-Controlled Phase 3 Evaluation of the Efficacy and Safety of LNZ101 and LNZ100 for the Treatment of Presbyopia. Clinicaltrials.gov. Accessed August 22, 2025.

Prepared October 2025. Contact person: Matthew A. Fuller, Pharm.D., BCPP, National PBM Clinical Pharmacy Program Manager, VA Pharmacy Benefits Management Services (12PBM)
