

# Medical Necessity Criteria

## Qlosi, Vizz, Vuity

### Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name	Dosage Form
Qlosi	pilocarpine hydrochloride	ophthalmic solution
Vizz	aceclidine	ophthalmic solution
Vuity	pilocarpine hydrochloride	ophthalmic solution

### Indications

#### FDA-approved Indications

##### Qlosi

Qlosi is indicated for the treatment of presbyopia in adults.

##### Vizz

Vizz is indicated for the treatment of presbyopia in adults.

##### Vuity

Vuity is indicated for the treatment of presbyopia in adults.

# Coverage Criteria

## Presbyopia

Authorization may be granted when the requested drug is being prescribed for the treatment of presbyopia in an adult patient when ALL of the following criteria are met:

- The patient has NOT been receiving the requested drug for at least 14 days.
- The presbyopia impacts the patient's activities of daily living to the point where pharmacologic intervention is required. [ACTION REQUIRED: Documentation is required for approval.]

# Continuation of Therapy

## Presbyopia

Authorization may be granted when the requested drug is being prescribed for the treatment of presbyopia in an adult patient when ALL of the following criteria are met:

- The patient has been receiving the requested drug for at least 14 days.
- The patient has demonstrated improvement from baseline presbyopia including gaining 3 lines or more in binocular distance corrected near visual acuity, without losing more than 1 line of corrected distance visual acuity. [ACTION REQUIRED: Documentation is required for approval.]

# Quantity Limits Apply

The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

The duration of 19 days is used for a 25-day fill period and 57 days is used for a 75-day fill period to allow time for refill processing.

For new starts, the intent is for prescriptions of the requested drug to be filled one fill at a time; there should be no 3-month supplies filled for new starts.

Drug	1 Month Limit	3 Months Limit
Qlosi 0.4% Ophthalmic Solution (pilocarpine hydrochloride ophthalmic solution)	60 single-patient use vials (12 pouches) / 25 days	180 single-patient use vials (36 pouches) / 75 days

Drug	1 Month Limit	3 Months Limit
Vizz 1.44% Ophthalmic Solution (aceclidine ophthalmic solution)	25 single-dose vials (5 pouches) / 19 days	75 single-dose vials (15 pouches) / 57 days
Vuity 1.25% Ophthalmic Solution (pilocarpine hydrochloride ophthalmic solution)	5 mL / 19 days	15 mL / 57 days

## Duration of Approval (DOA)

- 5132-C: Initial therapy DOA: 2 months; Continuation of therapy DOA: 12 months

## References

1. Qlosi [package insert]. Ponte Vedra, FL: Orasis Pharmaceuticals, Ltd.; October 2023.
2. Vizz [package insert]. Solana Beach, CA: LENZ Therapeutics, Inc.; July 2025.
3. Vuuity [package insert]. North Chicago, IL: AbbVie Inc.; March 2023.
4. Lexicomp Online, Lexi-Drugs Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed October 3, 2024.
5. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 10/03/2024).
6. Jacobs DS, Afshari NA, Bishop RJ, et al. Refractive Errors Preferred Practice Pattern. *Ophthalmology*. 2023;130(3):P1-P60.
7. Pharmacy Auditing and Dispensing Job Aid: Billing Other Dosage Forms. Centers for Medicare and Medicaid Services. December 2015.
8. Waring GO 4th, Price FW Jr, Wirta D, et al. Safety and Efficacy of AGN-190584 in Individuals With Presbyopia: The GEMINI 1 Phase 3 Randomized Clinical Trial. *JAMA Ophthalmology*. 2022;140(4):363-371.
9. Clinicaltrials.gov. Allergan. Phase 3 Efficacy Study of AGN-190584 in Participants with Presbyopia (GEMINI 2). Last Updated December 2022. Retrieved from: <https://clinicaltrials.gov/ct2/show/NCT03857542?term=NCT03857542>. Accessed October 3, 2024.
10. Clinicaltrials.gov. Allergan. A Study to Assess Safety and Efficacy in Participants Age 40 to 55 with Presbyopia (Old Eye) Who Receive AGN-190584 in Both Eyes Twice Daily (Virgo). Last Updated: March 2023. Retrieved from: <https://clinicaltrials.gov/ct2/show/NCT04983589>. Accessed October 3, 2024.
11. Jacobs DS, Lee JK, Shen TT, et al. Refractive Surgery Preferred Practice Pattern. *Ophthalmology*. 2023;130(3):P61-P135.