Reference number(s)
5054-C

Initial Prior Authorization with Quantity Limit
Qlosi, 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
Qlosi	pilocarpine hydrochloride ophthalmic solution
Vuity	pilocarpine hydrochloride ophthalmic solution

Indications

FDA-approved Indications

Qlosi

Qlosi 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 the following criteria is 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

Quantity Limit

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 mail limit will be the same as the retail limit. The intent is for prescriptions of the requested drug to be filled one fill at a time for new starts, even if filled at mail order; there should be no 3-month supplies filled for new starts.

Drug	**1 Month Limit**	**3 Month 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
Vuity 1.25% Ophthalmic Solution (pilocarpine hydrochloride ophthalmic solution)	5 mL / 19 days	15 mL / 57 days

Reference number(s)
5054-C

Duration of Approval (DOA)

- 5054-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.
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4. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 08/04/2023).
5. Jacobs DS, Afshari NA, Bishop RJ, et al. Refractive Errors Preferred Practice Pattern. Ophthalmology. 2023;130(3): P1-P60.
6. Pharmacy Auditing and Dispensing Job Aid: Billing Other Dosage Forms. Centers for Medicare and Medicaid Services. December 2015.
7. 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.
8. 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 September 5, 2023.
9. Clinicaltrials.gov. Allergan. 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://class.clinicaltrials.gov/ct2/show/NCT04983589. Accessed September 05, 2023.
10. Jacobs DS, Lee JK, Shen TT, et al. Refractive Surgery Preferred Practice Pattern. Ophthalmology. 2023;130(3): P61-P135.