Reference number(s)
5132-C

Medical Necessity Criteria
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	Dosage Form
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 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
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

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4. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 10/03/2024).
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 October 3, 2024.
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://clinicaltrials.gov/ct2/show/NCT04983589. Accessed October 3, 2024.
10. Jacobs DS, Lee JK, Shen TT, et al. Refractive Surgery Preferred Practice Pattern. Ophthalmology. 2023;130(3): P61-P135.

Document History

Written by: UM Development (SDL)

Date Written: 01/2022 (Created from 5054-C for NTMB use)

Revised: (ASA) 10/2022 (no clinical changes), 03/2023 (adjusted QL to allow for 4 drops/day and new package size [5mL]); (DRS) 10/2023 (off-cycle: added Qlosi); (KEJ/DRS) 10/2023 (annual: no clinical changes); (NSS) 10/2024 (no clinical changes)

Reviewed: Medical Affairs: (CHART) 10/27/2022, 04/20/2023, 10/26/2023, 11/09/2023, 10/24/2024

External Review: 02/2022 (FYI), 12/2022, 06/2023 (FYI), 12/2023, 12/2024

CRITERIA FOR APPROVAL

Reference number(s)
5132-C

1	Is the requested drug being prescribed for the treatment of presbyopia in an adult patient? [If Yes, then go to 2. If No, then no further questions.]	Yes	No
2	Has the patient been receiving the requested drug for at least 14 days? [If Yes, then go to 3. If No, then go to 6.]	Yes	No
3	Has the patient 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: If yes, then documentation is required for approval. Document the improvement from baseline presbyopia: _____ [If Yes, then go to 4. If No, then no further questions.]	Yes	No
4	Has documentation showing the patient's 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 been submitted to CVS Health? [If Yes, then go to 5. If No, then no further questions.] Tech Note: Documentation of the patient's 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 is required for approval.	Yes	No
5	Does the patient require MORE than the plan allowance of any of the following: A) 2 single-patient use vials per day of Qlosi, B) 4 drops per day of Vuity? [No further questions] RPh Note: If yes, then deny and enter a partial approval per Quantity Limit Chart.	Yes	No
6	Does the patient's diagnosis impact activities of daily living to the point where pharmacologic intervention is required? ACTION REQUIRED: If yes, then documentation is required for approval. Document the reasoning for intervention beyond non-pharmacologic treatment (e.g., reading glasses, bifocals, trifocals or progressive lenses, contact lenses): _____ [If Yes, then go to 7. If No, then no further questions.]	Yes	No
7	Has documentation of the patient's need for intervention beyond non-pharmacologic treatment (e.g., reading glasses, bifocals, trifocals or progressive lenses, contact lenses) been submitted to CVS Health?	Yes	No

[If Yes, then go to 8. If No, then no further questions.]

Tech Note: Documentation of the patient's need for intervention beyond non-pharmacologic treatment is required for approval.

8 Does the patient require MORE than the plan allowance of any of the following: A) 2 single-patient use vials per day of Qlosi, B) 4 drops per day of Vuity? [No further questions] Yes No

RPh Note: If yes, then deny and enter a partial approval per Quantity Limit Chart.

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS**
1.	Go to 2	Deny	Your plan only covers this drug when it is used for certain health conditions. Covered use is presbyopia (age-related loss of vision for nearby objects) in adults. Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Diagnosis]
2.	Go to 3	Go to 6	
3.	Go to 4	Deny	Your plan only covers this drug if it works well for you. We have denied your request because the drug did not work well for you. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Continuation: Efficacy]

4.	Go to 5	Deny	Your plan only covers this drug when records showing improvement in your vision are sent to us. Your records must be provided and must show what your doctor tells us. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Continuation Documentation]
5.	[Please select the appropriate denial close option. For the denial verbiage, only include the requested drug. Remove all other drugs from verbiage.]. Deny	[PA approved for 12 months. Approve per Quantity Limit Chart.]. Approve, 12 Months	We have denied your request because it is to take more drug each time, or more often than the amount your plan covers (dosing limit). We reviewed the information we had. We have partially approved your request for this drug up to the amount your plan covers (2 single-patient use vials per day for Qlosi, or 4 drops per day for Vuity). Your request for use of this drug at a higher dose or more often has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Dosing, Exceeds Max Limit, Partial denial]
6.	Go to 7	Deny	Your plan only covers this drug if your condition affects your activities of daily living. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Disease category/stage/severity]

7.	Go to 8	Deny	Your plan only covers this drug when records showing your condition affects your activities of daily living are sent to us. Your records must be provided and must show what your doctor tells us. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Documentation]
8.	[Please select the appropriate denial close option. For the denial verbiage, only include the requested drug. Remove all other drugs from verbiage.]. Deny	[PA approved for 2 months. Approve per Quantity Limit Chart; For new starts: there should be no 3 month supplies filled.]. Approve, 2 Months	We have denied your request because it is to take more drug each time, or more often than the amount your plan covers (dosing limit). We reviewed the information we had. We have partially approved your request for this drug up to the amount your plan covers (2 single-patient use vials per day for Qlosi, or 4 drops per day for Vuity). Your request for use of this drug at a higher dose or more often has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Dosing, Exceeds Max Limit, Partial denial]