Clinical Policy: Pilocarpine (Qlosi, Vuity)

Reference Number: PA.CP.PMN.270
Effective Date: 11/2024
Last Review Date: 10/2024

Description
Pilocarpine (Qlosi™, Vuity®) is a cholinergic muscarinic receptor agonist.

FDA Approved Indication(s)
Qlosi and Vuity are indicated for the treatment of presbyopia in adults.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness® that Qlosi and Vuity are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Diagnosis (must meet all)**:**

1. Diagnosis of presbyopia;
2. Prescribed by or in consultation with an optometrist or ophthalmologist;
3. Member meets one of the following at the time of therapy initiation (a or b):
   a. Vuity: Age between 40 and 55 years;
   b. Qlosi: Age between 45 and 64 years;
4. Failure of corrective eyeglasses or contact lenses to resolve the presbyopia symptoms, unless contraindicated or clinically significant adverse effects are experienced;
5. Member does not have glaucoma or ocular hypertension;
6. Requested agent is not prescribed concurrently with any other ophthalmic pilocarpine formulation;
7. Dose does not exceed one of the following (a or b):
   a. Vuity: 1 drop per eye per day, followed by an additional dose in each eye administered 3 to 6 hours after first dose;
   b. Qlosi: 1 drop per eye per day, followed by an additional dose administered 2 to 3 hours after first dose.

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

A. Diagnosis (must meet all)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies;

2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed one of the following (a or b):
   a. Vuity: 1 drop per eye per day, followed by an additional dose in each eye administered 3 to 6 hours after first dose;
   b. Qlosi: 1 drop per eye per day, followed by an additional dose administered 2 to 3 hours after first dose.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): known hypersensitivity to the active ingredient or to any of the excipients
- Boxed warning(s): none reported

V. Dosage and Administration

Drug Name	Dosing Regimen	Maximum Dose
Pilocarpine hydrochloride (Vuity)	1 drop per eye per day; a second dose (one additional drop in each eye) may be administered 3-6 hours after the first dose	2 drops per eye/day
Pilocarpine hydrochloride (Qlosi)	1 drop per eye per day; a second dose (one additional drop in each eye) may be administered 2-3 hours after the first dose for an effect up to 8 hours	2 drops per eye/day

VI. Product Availability

Drug Name	Availability
Pilocarpine (Vuity)	Ophthalmic solution bottle: 1.25%
Pilocarpine (Qlosi)	Ophthalmic solution single-patient-use vials: 0.4%

VII. References

1. Vuity Prescribing Information. North Chicago, IL: AbbVie Inc.; March 2023. Available at: https://www.rxabbvie.com/pdf/vuity_pi.pdf. Accessed July 19, 2024.
2. Qlosi Prescribing Information. Ponte Vedra, FL: Orasis Pharmaceuticals.; October 2023. Available at: https://qlosi.com/wp-content/uploads/2023/10/QLOSI-NDA-PI-Final-1.pdf. Accessed July 19, 2024.
3. ClinicalTrials.gov. NCT03804268. Phase 3 efficacy study of AGN-190584 in participants with presbyopia (GEMINI 1). Available at: https://clinicaltrials.gov/ct2/show/NCT03804268?term=AGN-190584&cond=presbyopia&draw=2&rank=3. Accessed August 19, 2024.
4. ClinicalTrials.gov. NCT03857542. A Phase 3 efficacy study of AGN-190584 in participants with presbyopia (GEMINI 2). Available at: https://clinicaltrials.gov/ct2/show/NCT03857542?term=AGN-190584&cond=presbyopia&draw=2&rank=2. Accessed August 19, 2024.
5. Presbyopia. American Academy of Ophthalmology review March 4, 2024. Available at: https://eyewiki.org/Presbyopia#Management. Accessed August 19, 2024.

Reviews, Revisions, and Approvals	Date
Policy created	10/2024