Pharmacy Policy Bulletin: Qlosi and Vuity (pilocarpine hydrochloride) – Commercial and Healthcare Reform	
Number: J-1162	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.):** **1.** Other Managed Prior Authorization = Yes w/ Prior Authorization **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-1162-004	**Original Date:** 12/01/2021
Effective Date: 02/04/2025	**Review Date:** 12/06/2023

Drugs Product(s):	• Qlosi (pilocarpine hydrochloride) • Vuity (pilocarpine hydrochloride)
FDA-Approved Indication(s):	• Treatment of presbyopia in adults.

Background:	• Qlosi and Vuity are ophthalmic solutions that activate muscarinic receptors located at smooth muscles. The iris sphincter muscle is constricted to improve near and intermediate visual acuity while maintaining some pupillary response to light. Qlosi and Vuity cause ciliary muscle contraction and may shift the eye to a more myopic state. • Presbyopia is age-related blurry near vision. The eye's ability to focus on near objects is reduced because the clear lens behind the iris does not change shape as easily. It impacts those 40 years of age and older. • If a person develops presbyopia before the age of 40 then it is referred to as premature presbyopia. Vuity was only studied in participants aged 40 to 55 years old with presbyopia. Qlosi was only studied in participants aged 45 to 64 years old with presbyopia. • The mainstay correction method for presbyopia includes wearing corrective eyeglasses or contact lens. Eyeglasses are simple, safe, and durable way to correct vision problems caused by presbyopia. Depending on the patient, over-the-counter or prescription eyeglasses can be used. For those who do not want to wear eyeglasses, contact lenses are an option. Contact lenses are not suitable for patients with certain conditions related to the eyelids, tear ducts, or surfaces of the eyes such as dry eye disease. Vuity and Qlosi were found to work in 15 or 20 minutes after administration and last for up to 6 or 8 hours, respectively, and can be administered daily while eyeglasses and contact lenses work immediately and last for however long they are worn. Additionally, eye drops may be a difficult formulation for seniors to administer, due to shaky hands and needing hand-eye coordination. While this consideration may not affect

	younger patients with presbyopia, those who are older may prefer to continue wearing eyeglasses.
	• Prescribing Considerations:
	  ○ Presbyopia occurs when the eye's lens loses flexibility. Farsightedness/hyperopia occurs when the eyeball is too short.
	  ○ Presbyopia does not occur in the pediatric population.
	  ○ Contact lens wearers should be advised to remove their lenses prior to the instillation of Qlosi or Vuity and to wait 10 minutes after dosing before reinserting their contact lenses.

Approval Criteria

I. Initial Authorization

When a benefit, coverage of Qlosi or Vuity may be approved when all of the following criteria are met **(A., B., and C.)**:

A. The member meets one (1) of the following criteria **(1. or 2.)**:
  1. If the request is for Qlosi, the member is 45 years of age or older.
  2. If the request is for Vuity, the member is 40 years of age or older.

B. The member has a diagnosis of presbyopia (ICD-10: H52.4).

C. The prescriber attests the member has experienced therapeutic failure to one (1) of the following products, or all are contraindicated **(1. or 2.)**:
  1. Eye glasses
  2. Contact lenses

II. Reauthorization

When a benefit, reauthorization of Qlosi or Vuity may be approved when the following criterion is met **(A.)**:

A. The prescriber attests that the member has experienced positive clinical response to therapy.

III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and HCR Plans: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

None.

References:

1. Vuity [package insert]. North Chicago, IL: Allergan; April 2023.
2. Qlosi [package insert]. Ponte Vedra, FL: Orasis Pharmaceuticals, Ltd.; October 2023.
3. American Academy of Ophthalmology. Presbyopia Treatment. Available at: https://www.aao.org/eye-health/diseases/presbyopia-treatment. Accessed October 26, 2023.

Pharmacy policies do not constitute medical advice, nor are they intended to govern physicians' prescribing or the practice of medicine. They are intended to reflect Highmark's coverage and reimbursement guidelines. Coverage may vary for individual members, based on the terms of the benefit contract.