

# MEDICAL NECESSITY CRITERIA

| DRUG CLASS                                                                                | MEDICAL NECESSITY CRITERIA                                                                                                                      |
|-------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------|
| BRAND NAME<br>(generic)                                                                   | <p><b>QLOSI</b><br/>(pilocarpine hydrochloride ophthalmic solution)</p> <p><b>VUITY</b><br/>(pilocarpine hydrochloride ophthalmic solution)</p> |
| <p><b>Status: CVS Caremark® Criteria</b><br/> <b>Type: Medical Necessity Criteria</b></p> |                                                                                                                                                 |

## POLICY

### 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

The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug is being prescribed for the treatment of presbyopia in an adult patient  
**AND**
  - The patient has NOT been receiving the requested drug for at least 14 days  
**AND**
    - The presbyopia impacts the patient's activities of daily living to the point where pharmacologic intervention is required. [Documentation is required for approval]
- OR**
  - The patient has been receiving the requested drug for at least 14 days  
**AND**
    - 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. [Documentation is required for approval]

Quantity Limits apply.

| <u>QUANTITY LIMIT</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                        |                                                         |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------|---------------------------------------------------------|
| Drug                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 1 Month Limit                                          | 3 Month Limit***                                        |
| Qlosi 0.4% Ophthalmic Solution<br>(pilocarpine hydrochloride ophthalmic solution)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 60 single-patient use vials<br>(12 pouches) / 25 days* | 180 single-patient use vials<br>(36 pouches) / 75 days* |
| Vuity 1.25% Ophthalmic Solution<br>(pilocarpine hydrochloride ophthalmic solution)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 5 mL / 19 days**                                       | 15 mL / 57 days**                                       |
| <p>*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.<br/> **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.<br/> ***For new starts, the mail limit will be the same as the retail limit. <b>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.</b></p> |                                                        |                                                         |

Qlosi, Vuity New to Market Medical Necessity Policy UDR 11-2023.docx

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Duration of Approval (DOA):

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

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