

Vuity™, Qlosi™ (pilocarpine ophthalmic solution)

Policy # 00776

Original Effective Date: 03/14/2022

Current Effective Date: 07/01/2025

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member’s contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider Vuity™[†], Qlosi™[†] (pilocarpine ophthalmic solution) to be **eligible for coverage**** when the patient selection criteria are met.

Patient Selection Criteria

Coverage eligibility for Vuity, Qlosi (pilocarpine ophthalmic solution) will be considered when the following criteria are met:

- Patient has a diagnosis of presbyopia; AND
- Patient is 18 years of age or older; AND
- Patient is unable to use corrective lenses (glasses or contacts) due to a physical or mental limitation.

*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Vuity, Qlosi (pilocarpine ophthalmic solution) when there is no evidence that the patient is unable to use corrective lenses (glasses or contacts) due to a physical or mental limitation to be **not medically necessary.****

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of Vuity, Qlosi (pilocarpine ophthalmic solution) in patients under the age of 18 OR for non-FDA approved indications to be **investigational.***

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Background/Overview

Vuity and Qlosi are cholinergic muscarinic receptor agonists indicated for the treatment of presbyopia in adults. Presbyopia is a non-refractive error that affects visual acuity. This occurs when the lens loses its accommodating power and can no longer focus on objects within an arm's length. Corrective lenses (i.e., glasses or contacts) are the first line of therapy for presbyopia.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Vuity, approved in late 2021, is a cholinergic muscarinic receptor agonist indicated for the treatment of presbyopia in adults. Qlosi, approved in October 2023, shares the same mechanism of action and indication as Vuity.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

The efficacy of Vuity for the treatment of presbyopia was demonstrated in two 30-Day Phase 3, randomized, double masked, vehicle-controlled studies, namely GEMINI 1 and GEMINI 2. A total of 750 participants aged 40 to 55 years old with presbyopia were randomized (375 to Vuity group) in two studies and participants were instructed to administer one drop of Vuity or vehicle once daily in each eye. In both studies, the proportion of participants gaining 3 lines or more in mesopic, high contrast, binocular distance corrected near visual acuity (DCNVA), without losing more than 1 line (5 letters) of corrected distance visual acuity (CDVA) with the same refractive correction was statistically significantly greater in the Vuity group compared to the vehicle group at Day 30, Hour 3 (31% in the Vuity group vs. 8% in the vehicle group in GEMINI 1; 26% in the Vuity group vs. 11% in the vehicle group in GEMINI 2).

The efficacy of Qlosi for the treatment of presbyopia was demonstrated in two Phase 3, randomized, double-masked, vehicle-controlled studies, namely NEAR-1 and NEAR-2. A total of 613 participants aged 45 to 64 years old with presbyopia were randomized (309 to Qlosi group) in these two studies. Participants were instructed to instill one drop of Qlosi or vehicle, in each eye, once in the morning and to repeat the instillation 2 to 3 hours later. Participants were treated for two weeks. Ophthalmic assessments were conducted on Day 1, 8 and 15 of the study at various timepoints.

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Responders demonstrated improvement by achieving a gain from baseline of 3 lines or more in near best distance-corrected visual acuity (BDCVA) at 40 centimeters without a loss of 1 line of more (≥ 5 letters) in BDCVA at 4 meters. Overall, the percentages of responders were consistently higher in the Qlosi group than in the vehicle group at each assessment day.

The purpose of this policy is to ensure that Vuity is being used for its FDA approved indication as well as to ensure that first-line treatment agents are utilized for the requested condition.

References

1. Vuity [package insert]. Abbvie. North Chicago, Illinois. Updated October 2021.
2. Visual Impairment in Adults: Refractive Disorders and Presbyopia. UpToDate. Accessed January 2022.
3. Qlosi [package insert]. Orasis Pharmaceuticals, Inc. Ponte Vedra, Florida. Updated March 2024.

Policy History

Original Effective Date: 03/14/2022

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02/03/2022	Medical Policy Committee review
02/09/2022	Medical Policy Implementation Committee approval. New policy.
02/02/2023	Medical Policy Committee review
02/08/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/01/2024	Medical Policy Committee review
02/14/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/06/2025	Medical Policy Committee review
02/12/2025	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/05/2025	Medical Policy Committee review.
06/11/2025	Medical Policy Implementation Committee approval. Added new product, Qlosi, to the policy with relevant criteria and background information. Title changed from “Vuity™ (pilocarpine ophthalmic solution 1.25%)” to “Vuity™, Qlosi™ (pilocarpine ophthalmic solution)”.

Next Scheduled Review Date: 06/2026

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and

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whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or

- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
1. Consultation with technology evaluation center(s);
 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. Reference to federal regulations.

****Medically Necessary (or “Medical Necessity”)** - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient’s health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.