

Pharmacotherapy for Presbyopia

Policy # 00776

Original Effective Date: 03/14/2022

Current Effective Date: 07/01/2026

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.

Investigational or experimental services are not covered. This includes any drug, device, procedure, or service provided under the investigational arm of a clinical trial or clinical study. These services are excluded from coverage under benefits.

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^{TM†} or its generic (pilocarpine 1.25% ophthalmic solution), Qlosi^{TM†} (pilocarpine 0.4 % ophthalmic solution), Vizz^{TM†} (aceclidine ophthalmic solution) or Yuvezzi^{TM†} (carbachol 2.75% and 0.1 % brimonidine ophthalmic solution) to be **eligible for coverage**** when the patient selection criteria are met.

Patient Selection Criteria

Coverage eligibility for Vuity or its generic (pilocarpine 1.25% ophthalmic solution), Qlosi (pilocarpine 0.4% ophthalmic solution), Vizz (aceclidine ophthalmic solution) or Yuvezzi (carbachol 2.75% and 0.1 % brimonidine 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; AND
*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*
- If the request is for brand Vuity, patient has tried and failed (e.g., intolerance or inadequate response) GENERIC pilocarpine 1.25% ophthalmic solution unless there is clinical evidence or patient history that suggests generic pilocarpine 1.25% ophthalmic solution will be ineffective or cause an adverse reaction to the patient.
*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*

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When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Vuity or its generic (pilocarpine 1.25% ophthalmic solution), Qlosi (pilocarpine 0.4% ophthalmic solution), Vizz (aceclidine ophthalmic solution) or Yuvezzi (carbachol 2.75% and 0.1 % brimonidine 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**.**

Based on review of available data, the Company considers the use of brand Vuity when the patient has not tried and failed generic pilocarpine 1.25% ophthalmic solution 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 or its generic (pilocarpine 1.25% ophthalmic solution), Qlosi (pilocarpine 0.4% ophthalmic solution), Vizz (aceclidine ophthalmic solution) or Yuvezzi (carbachol 2.75% and 0.1 % brimonidine ophthalmic solution) in patients under the age of 18 OR for non-FDA approved indications to be **investigational**.*

Background/Overview

Vuity, Qlosi, and Vizz are cholinergic muscarinic receptor agonists indicated for the treatment of presbyopia in adults. Yuvezzi is a combination of carbachol, a cholinergic agonist, and brimonidine, an alpha-adrenergic receptor agonist, and is also 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. In July 2025, a third cholinergic muscarinic receptor agonist, Vizz, was approved for the treatment of presbyopia in adults. Yuvezzi, approved in January 2026, is a combination of carbachol, a cholinergic agonist, and brimonidine, an alpha-adrenergic receptor agonist, indicated for the treatment of presbyopia in adults.

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.

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Vuity

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).

Qlosi

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.

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 or 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.

Vizz

The efficacy of Vizz for the treatment of presbyopia was demonstrated in two, randomized, double masked, controlled studies, CLARITY-1 and CLARITY-2. A total of 466 participants aged 45 to 75 years old with presbyopia were randomized. Participants had a refractive range from -4.00 to +1.00 D sphere, with astigmatism up to 2.00 D, and a spherical equivalent no more myopic than -4.00 D. Both studies included participants who were post-refractive surgery and/or pseudophakic. Participants were instructed to instill 2 drops of Vizz (or control) in each eye once daily, one drop in each eye followed by a second drop in each eye two minutes later. Participants were treated for 42 days. Ophthalmic efficacy assessments were conducted on Day 1, Day 15, and Day 28 of the study at various timepoints through 10 hours post dose.

In each study, the proportion of participants gaining 3 lines or more in high contrast, distance corrected, near visual acuity (DCNVA) at 40 cm, without loss of 1 line or more (≥ 5 letters) of distance corrected, distance visual acuity (DCDVA) at 4 meters was statistically significantly greater in the Vizz group compared to the control group at Day 1, Hour 3.

Yuvezzi

The efficacy of Yuvezzi for the treatment of presbyopia was demonstrated in two Phase 3, randomized, double-masked, controlled studies in participants 45 to 80 years old with presbyopia. BRIO I was a crossover study in which 182 participants received a single administration of 1 drop

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of Yuvezzi, carbachol, and brimonidine tartrate in each eye with at least 3 days between treatments and was designed to evaluate the superiority of Yuvezzi over either active monotherapy. In BRIO II, 436 participants were randomized for a single administration of 1 drop of Yuvezzi or vehicle (218 to each group) in each eye. In addition, participants administered 1 drop of Yuvezzi or vehicle once daily for 6 months followed by a 6-month open label extension. Both studies included participants who were post-refractive surgery and/or pseudophakic.

Across the pivotal studies, responders were defined as participants achieving a gain from baseline of 3 lines (15 letters) or more in binocular uncorrected near visual acuity (BUCNVA) without a loss of 1 line (5 letters) or more in binocular uncorrected distance visual acuity (BUCDVA) under mesopic conditions. The proportion of responders was consistently greater with Yuvezzi compared to control (vehicle) and generally higher than each individual component, with statistically significant differences observed from 30 minutes through multiple post-dose timepoints, demonstrating rapid onset and sustained efficacy over several hours.

The purpose of this policy is to ensure that Vuity, Qlosi, Vizz, and Yuvezzi are being used for their 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.
4. Vizz [package insert]. Lenz Therapeutics, Inc. Solana Beach, California. Updated July 2025.
5. Yuvezzi [package insert]. Visus Therapeutics, Inc. Seattle, Washington. Updated January 2026.

Policy History

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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.

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- 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)”.
- 11/06/2025 Medical Policy Committee review.
- 11/12/2025 Medical Policy Implementation Committee approval. Added new product, Vizz, to the policy with relevant criteria and background information. Updated criteria to include generic pilocarpine 1.25% ophthalmic solution and require trial of the generic prior to brand Vuity. Title changed from “Vuity™, Qlosi™ (pilocarpine ophthalmic solution)” to “Pharmacotherapy for Presbyopia”.
- 06/04/2026 Medical Policy Committee review
- 06/10/2026 Medical Policy Implementation Committee approval. Added new product, Yuvezzi, to the policy with relevant criteria and background information.

Next Scheduled Review Date: 06/2027

***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 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.

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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.

NOTICE: If an authorization for an ongoing course of treatment has been provided to a member and the member changes from one health plan to another health plan (e.g., a member moves from carrier A to Louisiana Blue), Louisiana Blue may honor the previous health plan’s authorization for the same service under the same type of in-network benefit for a 90-day transition period. Documentation of the authorization for the ongoing course of treatment from the previous health plan must be provided to us by the member or their provider and the services provided for the course of treatment must otherwise be a covered service under the Louisiana Blue health plan. This provision does not apply to medications covered under the plan’s pharmacy benefit.