Pharmacy Medical Necessity Guidelines: Pilocarpine ophthalmic solution (Vuity)

Effective: January 1, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

Presbyopia is the inability to see objects at arm's length or closer. Presbyopia is often treated with glasses. Presbyopia is associated with the aging process, typically beginning after age 40.

Pilocarpine hydrochloride (HCl) 1.25% ophthalmic solution (Vuity) is a cholinergic muscarinic receptor agonist approved by the Food and Drug Administration (FDA) for the treatment of presbyopia in adults. The recommended dose is one drop in each eye once daily. A second dose of on additional drop in each eye may be administered 3-6 hours after the first dose. If a member is administering more than one ophthalmic product, it is recommended that the products be administered 5 minutes apart.

Pilocarpine HCl 1.25% ophthalmic solution was studied in two 30-day phase 3, randomized, double-blind, vehicle-controlled studies. Participants were between the ages of 40 and 55 years of age with a diagnosis of presbyopia. Compared to vehicle group, the pilocarpine HCl 1.25% group had a statistically significantly greater proportion of patients gaining three lines or more in mesopic, high contrast, binocular distance corrected near visual acuity without losing more than one line (five letters) of corrected distance visual acuity with the same refractive correction.

Caution should be used with night driving and when hazardous activities are being taken in poor illumination.

Pilocarpine HCl 1.25% ophthalmic solution is available as 2.5 mL in a 5 mL bottle.

COVERAGE GUIDELINES

The plan may authorize coverage of pilocarpine HCl 1.25% ophthalmic solution (Vuity) when the following criteria are met and limitations do not apply:

1. The Member has a diagnosis of presbyopia

AND

2. The prescriber is an optometrist or ophthalmologist or a specialist consult note is provided

AND

3. The Member is 40 years of age or older

AND

4. The provider submits a clinical rationale why the member cannot use corrective lenses

LIMITATIONS

1. Pilocarpine HCl 1.25% ophthalmic solution is limited to 0.133 mL/day (one 2.5 mL bottle per 18 days)
2. Requests for brand-name products, which have AB-rated generics, will be reviewed according to Brand Name criteria.

CODES

None

REFERENCES

1. Mian SI. Visual impairment in adults: refractive disorders and presbyopia. UpToDate. Accessed 24 March 2022.
2. Vuity (pilocarpine HCl) ophthalmic solution [prescribing information]. North Chicago, IL: AbbVie Inc; March 2023.

APPROVAL HISTORY

October 11, 2022: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. June 13, 2023: No changes.
2. March 12, 2024: Effective April 1, 2024, updated RxUM fax number.
3. December 2025 E-Vote: Effective 1/1/26, updated MNG title to "Pilocarpine ophthalmic solution (Vuity)" and updated reference to Vuity as generic name pilocarpine ophthalmic solution within the Overview, Coverage Guidelines, and Limitations sections to reflect generic availability of Vuity. Added the following language to Limitations section: Requests for brand-name products, which have AB-rated generics, will be reviewed according to Brand Name criteria.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.