

<b>Clinical Policy Title:</b>	pilocarpine hydrochloride
<b>Policy Number:</b>	RxA.768
<b>Drug(s) Applied:</b>	Vuity™
<b>Original Policy Date:</b>	07/18/2022
<b>Last Review Date:</b>	08/28/2024
<b>Line of Business Policy Applies to:</b>	All lines of business (except Medicare)

## Criteria

### I. Initial Approval Criteria

#### A. Presbyopia (must meet all):

1. Diagnosis of presbyopia;
2. Failure of corrective eyeglasses or contact lenses to resolve the presbyopia symptoms, unless contraindicated or clinically significant adverse effects are experienced;
3. Member does not have glaucoma or ocular hypertension;
4. Vuity™ is not prescribed concurrently with any other ophthalmic pilocarpine formulation.

#### Approval Duration

**All Lines of Business (except Medicare):** 6 months

### II. Continued Therapy Approval

#### A. Presbyopia (must meet all):

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

#### Approval Duration

**All Lines of Business (except Medicare):** 12 months

## References

1. ClinicalTrials.gov. NCT03857542. A Phase 3 efficacy study of AGN-190584 in participants with presbyopia (GEMINI 2). Available at: <https://clinicaltrials.gov/ct2/show/NCT03857542?term=AGN190584&cond=presbyopia&draw=2&rank=2>. Accessed August 28, 2024.
2. ClinicalTrials.gov. NCT03804268. Phase 3 efficacy study of AGN-190584 in participants with presbyopia (GEMINI 1). Available at: <https://clinicaltrials.gov/ct2/show/NCT03804268?term=AGN190584&cond=presbyopia&draw=2&rank=3>. Accessed August 28, 2024.
3. Presbyopia. American Academy of Ophthalmology review. November 2022. Available at: <https://eyewiki.org/Presbyopia#Management>. Accessed August 28, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	06/01/2022	07/18/2022

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

<p>Policy was reviewed:</p> <ol style="list-style-type: none"> <li>References were reviewed and updated.</li> </ol>	06/01/2023	7/13/2023
<p>Policy was reviewed.</p>	10/19/2023	10/19/2023
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> <li>Removed age restrictions.</li> <li>Removed prescriber restrictions.</li> <li>Removed dose restrictions.</li> <li>Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days.</li> <li>Removed reauthorization requirement for positive response to therapy.</li> <li>Updated approval duration verbiage.</li> <li>References were reviewed and updated.</li> </ol>	08/28/2024	09/13/2024