Clinical Policy: Pilocarpine (Vuity)

Reference Number: ERX.NPA.161
Effective Date: 12.01.21
Last Review Date: 11.22
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Pilocarpine (Vuity™) is a cholinergic muscarinic receptor agonist.

FDA Approved Indication(s)
Vuity is indicated for the treatment of presbyopia in adults.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Vuity is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

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

1. Diagnosis of presbyopia;
2. Prescribed by or in consultation with an optometrist or ophthalmologist;
3. Age between 40 and 55 years at the time of therapy initiation;
4. Failure of corrective eyeglasses or contact lenses to resolve the presbyopia symptoms, unless contraindicated or clinically significant adverse effects are experienced;
5. Member does not have glaucoma or ocular hypertension;
6. Vuity is not prescribed concurrently with any other ophthalmic pilocarpine formulation;
7. Dose does not exceed 1 drop per eye per day.

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 1 drop per eye per day.

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): known hypersensitivity to pilocarpine or to any of the excipients
- Boxed warning(s): none reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Presbyopia	1 drop per eye per day	1 drop per eye per day

VI. Product Availability

Ophthalmic solution: 1.25% (2.5 mL)

VII. References

1. Vuity Prescribing Information. North Chicago, IL: AbbVie Inc.; October 2021. Available at: https://www.rxabbvie.com/pdf/vuity_pi.pdf. Accessed July 18, 2022.
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=AGN-190584&cond=presbyopia&draw=2&rank=3. Accessed July 18, 2022.
3. 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=AGN-190584&cond=presbyopia&draw=2&rank=2. Accessed July 18, 2022.
4. Presbyopia. American Academy of Ophthalmology review October 9, 2019. Available at: https://eyewiki.org/Presbyopia#Management. Accessed July 18, 2022.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	10.29.21	11.21
4Q 2022 annual review: no significant changes; references reviewed and updated.	07.18.22	11.22

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional

medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.