

Vuity (pilocarpine)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	6 months

Medications	Quantity Limit
Vuity (pilocarpine) ophthalmic solution	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Vuity (pilocarpine) may be approved if the following criteria are met:

- I. Individual is 40 to 55 years of age (GEMINI I, GEMINI 2); **AND**
- II. Documentation is provided that individual has a diagnosis of presbyopia; **AND**
- III. Documentation is provided that individual has had a trial and inadequate response or intolerance to corrective eyeglasses or contact lenses; **AND**
- IV. Documentation is provided for why Vuity is clinically necessary and not for convenience.

Vuity (pilocarpine ophthalmic solution) may not be approved for the following (GEMINI I, GEMINI 2):

- I. Individual has a diagnosis of glaucoma (any type) or ocular hypertension; **OR**
- II. Individual has severe dry eye disease (defined as total corneal staining \geq grade 3 on the 5-point Oxford scale and an ocular surface disease index (OSDI) score of > 33); **OR**
- III. Individual is using in combination with other pilocarpine ophthalmic agents; **OR**
- IV. Individual is using for cosmetic indications.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: January 15, 2022.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
5. NCT03857542. A Phase 3 Efficacy Study of Pilocarpine HCl Ophthalmic Solution (AGN-190584) in Participants With Presbyopia (GEMINI 2). ClinicalTrials.gov identifier. Updated December 29, 2021. Accessed January 13, 2022. Available at <https://clinicaltrials.gov/ct2/show/results/NCT03857542?term=NCT03857542&draw=2&rank=1>.
6. NCT03804268. Efficacy Study of Pilocarpine HCl Ophthalmic Solution (AGN-190584) in Participants With Presbyopia (GEMINI 1). ClinicalTrials.gov identifier. Updated December 28, 2021. Accessed January 13, 2022. Available at <https://clinicaltrials.gov/ct2/show/results/NCT03804268?term=NCT03804268&draw=2&rank=1>.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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