



## Drug Coverage Policy

Effective Date .....06/01/2025

Coverage Policy Number.....IP0738

Policy Title.....Qlosi

### Qlosi

- Qlosi™ (pilocarpine HCL ophthalmic solution – Orasis Pharmaceuticals)

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#### **INSTRUCTIONS FOR USE**

*The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.*

### Coverage Policy

**Qlosi (pilocarpine HCL ophthalmic solution) for the treatment of presbyopia in adults is considered to be not medically necessary. Criteria will be updated as new published data are available.**

- 1. Presbyopia in adults.** Qlosi is FDA approved for the treatment of presbyopia in adults; however, only treatments that are required to diagnose or treat an illness, injury, disease or its symptoms are considered to be medically necessary.

## Overview

Qlosi is a cholinergic muscarinic receptor agonist indicated for the treatment of presbyopia in adults.<sup>1</sup>

### Disease Overview

Presbyopia is the irreversible loss of the accommodative ability of the eye that occurs due to aging. The average age of those first reporting symptoms of presbyopia is between 42 and 44 years of age with a complete loss of accommodation typically occurring between the ages of 50-55 years. This decline occurs as a natural result of aging and will ultimately affect any person reaching advanced enough age. Gradual onset of blurred near vision is often the first presenting symptom of presbyopia. Other symptoms commonly experienced include squinting, headaches secondary to eye strain, increased light requirement, and need to work from progressively greater distances. It is believed to stem from a gradual thickening and loss of flexibility of the natural lens inside your eye. This differs from astigmatism, nearsightedness and farsightedness, which are related to the shape of the eyeball and are caused by genetic and environmental factors.<sup>2,3</sup>

### Professional Societies/Organizations

**American Academy of Ophthalmology (AAO):** The AAO Preferred Practice Pattern® on Refractive Errors & Refractive Surgery (November 2017) states under Highlighted Findings and Recommendations for Care:<sup>4</sup>

- Qlosi is not addressed in guidelines
- Presbyopia can be managed by using eyeglasses or contact lenses (soft, rigid gas-permeable, aspheric bifocal or multifocal). Surgical management of presbyopia includes keratorefractive surgery, corneal inlays, or intraocular lens implantation (multifocal, accommodative, and extended depth of focus lenses)

## References

1. Qlosi™ ophthalmic solution [prescribing information]. Ponte Vedra, FL: Orasis Pharmaceuticals, Inc.; March 2024.
2. American Academy of Ophthalmology. EyeWiki®. Presbyopia. October 9, 2019. Accessed October 2021. Available at URL address: <https://eyewiki.org/Presbyopia>.
3. American Academy of Ophthalmology. EyeSmart®. What is Presbyopia? January 13, 2020. Accessed October 2021. Available at URL address: <https://www.aao.org/eye-health/diseases/what-is-presbyopia>.
4. American Academy of Ophthalmology (AAO). Clinical Statement. Amblyopia is a Medical Condition. April 2017. Accessed October 2021. Available at URL address: <https://www.aao.org/preferred-practice-pattern/refractive-errors-refractive-surgery-ppp-2017>.

## Revision Details

Type of Revision	Summary of Changes	Date
New	New policy	06/01/2025

The policy effective date is in force until updated or retired.

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