Clinical Guideline



Guideline Number: PG067, Ver. 4

olopatadine eye drops

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Olopatadine eye drops are FDA approved for the treatment of allergic conjunctivitis. Olopatadine is a selective histamine H1-antagonist that reduces histamine release and helps to prevent itching in the eye associated with allergic conjunctivitis. It is administered by instilling 1 drop into each affected eye daily. Olopatadine ophthalmic solution is available in 0.1%, 0.2% and 0.7% formulations.

Definitions

"Allergic conjunctivitis" refers to eye inflammation caused by an allergic reaction to substances like pollen or mold spores. Symptoms include itching or redness of the eyes.

"Histamine" refers to a chemical found in some of the body's cells and causes many allergic symptoms.

Medical Necessity Criteria for Authorization

The Plan considers <u>olopatadine eye drops</u> medically necessary when ALL of the following criteria are met:

- 1. The member is 2 years of age or older; **AND**
- 2. The member has a documented diagnosis of allergic conjunctivitis; AND
- 3. The member is unable to use, or has tried and failed ONE of the over-the-counter (OTC) alternatives listed below:
 - a. Olopatadine Hydrochloride 0.1% Ophthalmic Solution (Pataday Twice Daily Relief 0.1% Ophthalmic Solution); or
 - b. Olopatadine Hydrochloride 0.2% Ophthalmic Solution (Pataday Once Daily Relief 0.2% Ophthalmic Solution); or
 - c. Olopatadine Hydrochloride 0.7% Ophthalmic Solution (Pataday Once Daily Relief 0.7% Extra Strength Ophthalmic Solution).

If the above prior authorization criteria are met, Olopatadine eye drops will be approved for 12 months.

Experimental or Investigational / Not Medically Necessary

Olopatidine eye drops for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven.

References

- American Academy of Ophthalmology: Conjunctivitis Preferred Practice Patterns, 2018.
 Available at: https://www.aao.org/preferred-practice-pattern/conjunctivitis-ppp-2018. Published October 2018. Accessed 15 July 2021. doi:10.1016/j.ophtha.2018.10.020
- 2. Bielory, B., & Bielory, L. (2010). Atopic dermatitis and keratoconjunctivitis. Immunology and Allergy Clinics, 30(3), 323-336.
- 3. Bielory L, et al. An algorithm for the management of allergic conjunctivitis. Allergy & Asthma Proceedings. 2013;34(5):408-420. doi:10.2500/aap.2013.34.3695
- 4. Bielory L, et al. Delgado L, Katelaris CH, Leonardi A, Rosario N, Vichyanoud P. ICON: Diagnosis and management of allergic conjunctivitis. Ann Allergy Asthma Immunol. 2020;124(2):118-134. doi:10.1016/j.anai.2019.11.014
- 5. Olopatadine hydrochloride ophthalmic solution, 0.1% [prescribing information]. Mendham, NJ: Somerset Therapeutics, LLC; June 2016.
- 6. Olopatadine hydrochloride ophthalmic solution, 0.1% [prescribing information]. Morgantown, WV: Mylan; July 2017.
- 7. Olopatadine hydrochloride ophthalmic solution, 0.2% [prescribing information]. Lake Forest, IL: Akorn; December 2017.

- 8. Pataday 0.1% Twice a Day Relief (olopatadine hydrochloride) [prescribing information]. Fort Worth, TX: Alcon; November 2021.
- 9. Pataday 0.2% Once Daily Relief (olopatadine hydrochloride) [prescribing information]. Fort Worth, TX: Alcon; April 2021.
- 10. Pataday 0.7% Once Daily Relief (olopatadine hydrochloride) [prescribing information]. Fort Worth, TX: Alcon; April 2021.
- 11. Patanol (olopatadine hydrochloride) [prescribing information]. Fort Worth, TX: Alcon; April 2018.
- 12. Singh, K., Axelrod, S., & Bielory, L. (2010). The epidemiology of ocular and nasal allergy in the United States, 1988-1994. Journal of Allergy and Clinical Immunology, 126(4), 778-783.

Clinical Guideline Revision / History Information

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