



**UnitedHealthcare Individual & Family ACA Marketplace Plans
Clinical Pharmacy Program Guidelines for Ophthalmic Anti-allergy Agents**

Program	Step Therapy
Medication	Epinastine (generic Elestat)
Issue Date	9/2020
Pharmacy and Therapeutics Approval Date	11/2022
Effective Date	2/2023

1. Background:

Epinastine (generic Elestat) is an ophthalmic anti-allergy agent indicated for the treatment of itching of the eye associated with allergic conjunctivitis.

Step Therapy programs are utilized to encourage the use of lower cost alternatives for certain therapeutic classes. This program requires a member to try one alternative ophthalmic anti-allergy alternative – Azelastine (generic Optivar) – prior to receiving coverage for Epinastine (generic Elestat).

2. Coverage Criteria^a:

A. Authorization Criteria

1. **Epinastine Ophthalmic Solution** will be approved for patients who have a history of failure, contraindication, or intolerance to azelastine (generic Optivar).

Authorization will be issued for 12 months.

^a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:



1. Epinastine Ophthalmic Solution Prescribing Information. Defender SD Manufacturing, LLC, San Diego, CA. November 2021.
2. Azelastine Ophthalmic Solution Prescribing Information. Alembic Pharmaceuticals, Bridgewater, NJ. May 2022.

Program	Step Therapy – Ophthalmic Anti-allergy Agents
Change Control	
Date	Change
12/2009	Criteria were taken from the previously approved AmeriChoice policy. Policy was reformatted.
12/2010	Annual review, no change
3/2011	Annual review, no change
3/2012	Annual review, no change
3/2013	Annual review, no change
11/2016	Annual review, updated policy template and added standard authorization duration of 12 months
11/2017	Annual review. Updated references. Combined all requirements into one statement to align with standard language found in other policies.
11/2018	Annual review. Updated background and references.
12/2019	Annual review. Renamed policy from Optivar to Azelastine Ophthalmic Solution since only available as a generic. Updated criteria to remove automated step therapy language.
10/2020	Renamed C&S policy to Ophthalmic Anti-allergy Agents, revised background, removed azelastine as a target drug, added epinastine as a target drug stepping though azelastine, added specific step therapy exemption state mandates, and added epinastine reference.
12/2020	Removed unnecessary state mandate specific language pertaining to MD, OK, VA and left generalized state mandate language for PA team to reference state mandates grid as appropriate for UnitedHealthcare Value & Balance Exchange for 1/2021 implementation.
9/2021	Review for 2022 implementation. Removed markets in scope and step therapy detailed definition.
11/2022	Annual review, updated references.