

Drug Policy

Policy:	Tryptyr (acoltremon ophthalmic solution) 0.003%	Annual Review Date: 11/20/2025
		Last Revised Date: 11/20/2025

OVERVIEW

Tryptyr is an agonist of the transient receptor potential melastatin 8 (TRPM8) thermoreceptors, indicated for the treatment of dry eye disease. TRPM8 thermoreceptor stimulation has been shown to activate trigeminal nerve signaling leading to increased basal tear production. The exact mechanism of action for TRYPTYR in dry eye disease is unknown.

POLICY STATEMENT

This policy involves the use of Tryptyr. Prior authorization is recommended for pharmacy benefit coverage of Tryptyr. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Tryptyr as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Tryptyr be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Tryptyr is recommended in those who meet the following criteria:

1. Dry Eye Disease, Initial Therapy.

Criteria. *Patient must meet the following criteria (A, B, C, and D):*

- A. Patient is 18 years of age or older; AND
- B. Tryptyr is prescribed by or in consultation with an ophthalmologist, optometrist, or rheumatologist; AND
- C. The provider has administered testing for one of the following homeostasis markers with corresponding results (a, b, c, or d):
 - a. Schirmer's test (< 5 mm of wetting over 5 minutes), OR
 - b. Non-invasive tear breakup time (< 10 s), OR
 - c. Osmolarity (\geq 308 mOsm/L in either eye or interocular difference of $>$ 8 mOsm/L), OR
 - d. Ocular surface staining ($>$ 5 corneal spots, $>$ 9 conjunctival spots, or lid margin [\geq 2 mm length and \geq 25% width]); AND
- D. The patient has tried artificial tears.

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2. **Dry Eye Disease, Continuation of Therapy.**

Criteria. Patient must meet the following criteria (A, B, and C)

- A. The patient is 18 years of age or older; AND
- B. The medication is prescribed by or in consultation with an ophthalmologist, optometrist, or rheumatologist; AND
- C. The patient has had a beneficial response to therapy, including reduced eye irritation, dryness, red eyes, or burning).

Initial Approval/ Extended Approval.

A) Initial Approval:	1 year
B) Extended Approval:	1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Tryptyr has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. **Concomitant Use with Another Ophthalmic Cyclosporine Product, Miebo (perfluorohexyloctane ophthalmic solution), Tyrvaya (varenicline nasal solution), or Xiidra (lifitegrast ophthalmic solution).** There are no data to support the concomitant use of an ophthalmic cyclosporine product, Miebo, Tryptyr, Tyrvaya, or Xiidra.
Note: Ophthalmic cyclosporine products are Cequa, Restasis, and Vevye.
2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company.

Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Tryptyr [prescribing information]. Fort Worth, TX: Alcon Laboratories, Inc; May 2025.
2. American Academy of Ophthalmology cornea/external disease panel. Preferred practice pattern® guidelines. Dry eye syndrome. San Francisco, CA: American Academy of Ophthalmology; 2018. Available at: www.aao.org/ppp. Accessed on 12 September 2019.

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