# Clinical Policy: Ophthalmic Agents: Dry Eye Treatments

Reference Number: OH.PHAR.PPA.76
Effective Date: 01.20
Last Review Date: 06.22
Line of Business: Medicaid

Revision Log

**See Important Reminder at the end of this policy for important regulatory and legal information.**

## Description

**OPHTHALMIC AGENTS: Dry Eye Treatments**

| STEP THERAPY REQUIRED "PREFERRED" | PA REQUIRED "NON-PREFERRED" |
|---|---|
| RESTASIS® trays (cyclosporine) | CEQUA™ (cyclosporine)<br>EYSUVIS<br>RESTASIS® multi-dose (cyclosporine)<br>TYRVAYA nasal spray (varenicline)<br>XIIDRA™ (lifitegrast) |

**FDA approved indication(s)**

Restasis and Cequa are indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca.

Tyrvaya and Xiidra are indicated for the treatment of the signs and symptoms of dry eye disease (DED).

Eysuvis is indicated for the short-term (up to 2 weeks) treatment of signs and symptoms associated with dry eye disease, such as xerophthalmia.

## Policy/Criteria

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of Buckeye Health Plan, an affiliate of Centene Corporation® that Ophthalmic Agents: Dry Eye Treatments are **medically necessary** when the following criteria are met:

### I. Initial Approval Criteria

1. Prescribed indication is FDA-approved or supported by standard pharmacopeias;
2. Member must meet labeled age requirements for the medication;
3. Failure of ≥ 30 days of one preferred medication, unless member meets one of the following (a, b, or c):
    a. Allergy to preferred medications;
    b. Contraindication to or drug interaction with preferred medications;
    c. History of unacceptable/toxic side effects to preferred medications;
4. Failure of artificial tears or OTC dry eye drop in the previous 120 days, unless contraindicated or clinically significant adverse effects are experienced.

**Approval Duration: 14 days for Eysuvis; 12 months for all other agents**

### II. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy - CP.PMN.53 or evidence of coverage documents.

## III. Appendices/General Information

*Appendix A: Abbreviation/Acronym Key*
DED: dry eye disease
FDA: Food and Drug Administration

*Appendix B: Therapeutic Alternatives*
*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.*

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| Artificial tear products*<br>• Refresh P.M.® (artificial tear ophthalmic ointment)<br>• Systane® Nighttime (white petrolatum-mineral oil ophthalmic ointment)<br>• Nature's Tears® (hypromellose ophthalmic solution 0.4%)<br>• Artificial Tears (polyvinyl alcohol ophthalmic solution 1.4%)<br>• Lacri-Lube® (artificial tears ointment) | Solution/gel: 1-2 drops into the affected eye(s) 2-4 times/day as needed<br><br>Ointment: Apply small amount (~1/4 inch) to the inside of the lower eyelid 1-4 times/day as needed | Not applicable |

*Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.*
**Available over-the-counter in a number of preparations. This list is not all-inclusive*

*Appendix C: Contraindications/Boxed Warnings*
- Contraindication(s): active ocular infections and hypersensitivity
- Boxed warning(s): none reported

## IV. Dosage and Administration

| Drug | Dosing Regimen | Maximum Dose |
|---|---|---|
| Cequa | 1 drop in affected eye(s) BID approximately 12 hours apart | 2 drops/day per affected eye |
| Eysuvis | Various – depends on indication | 1-2 drops per eye four times daily for up to 2 weeks |
| Restasis | 1 drop in affected eye(s) BID approximately 12 hours apart | 2 drops/day per affected eye |
| Tyrvaya | 1 spray (0.03 mg) in each nostril BID, approximately 12 hours apart | 0.12 mg (4 sprays) intranasally/day |

| Drug | Dosing Regimen | Maximum Dose |
|---|---|---|
| Xiidra | 1 drop in each eye BID approximately 12 hours apart | 2 drops/day in each eye |

## V. Product Availability

| Drug | Availability |
|---|---|
| Cequa | Ophthalmic solution: 0.09% |
| Eysuvis | Ophthalmic suspension 0.25% |
| Restasis | MultiDose bottle Ophthalmic Emulsion: 0.05%, 5.5 mL total<br>Single use Vial Ophthalmic Emulsion: 0.05%, 0.4 mL each of 30 vials/tray and 60 vials/tray |
| Tyrvaya | 0.03 mg Nasal spray: 4.2 ml (0.6 mg/1 ml) |
| Xiidra | Ophthalmic solution: 5%, 0.2 mL containers (60 single-use containers/box) |

## VI. References

Refer to package inserts.

| Reviews, Revisions, and Approvals | Date | Approval Date |
|---|---|---|
| Policy created | 10.19 | |
| Annual review – no changes deemed necessary | 11.20 | |
| Added Eysuvis as Non-preferred, PA required agent, with a 14 day length of approval | 06.21 | |
| Added Tyrvaya to PA required – Non-preferred; updated approval duration to 12 months for all other agents excluding Eysuvis (14 day approval); updated criteria requiring failure of an artificial tear or OTC eye drop to be in previous 120 days; removed specific age limits and added statement that member must meet labeled age requirements for the medication. | 06.22 | |

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does

not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

**Note: For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.