

Initial Prior Authorization with Quantity Limit

Dry Eye Disease Agents

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

| Brand Name | Generic Name | Dosage Form |
|------------|-----------------------|-----------------------------|
| Cequa | cyclosporine | ophthalmic solution |
| Eysuvis | loteprednol etabonate | ophthalmic suspension 0.25% |
| Miebo | perfluorohexyloctane | ophthalmic solution |
| Restasis | cyclosporine | ophthalmic emulsion |
| Tryptyr | acoltremon | ophthalmic solution |
| Tyrvaya | varenicline | nasal spray solution |
| Veveye | cyclosporine | ophthalmic solution |
| Xiidra | lifitegrast | ophthalmic solution |

Indications

FDA-approved Indications

Cequa

Cequa ophthalmic solution is a calcineurin inhibitor immunosuppressant indicated to increase tear production in patients with keratoconjunctivitis sicca (dry eye).

Eysuvis

Eysuvis is a corticosteroid indicated for the short-term (up to two weeks) treatment of the signs and symptoms of dry eye disease.

Miebo

Miebo (perfluorohexyloctane ophthalmic solution) is indicated for the treatment of the signs and symptoms of dry eye disease (DED).

Restasis

Restasis ophthalmic emulsion is indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca. Increased tear production was not seen in patients currently taking topical anti-inflammatory drugs or using punctal plugs.

Tryptyr

Tryptyr is indicated for the treatment of the signs and symptoms of dry eye disease.

Tyrvaya

Tyrvaya (varenicline solution) nasal spray is indicated for the treatment of the signs and symptoms of dry eye disease.

Vevye

Vevye is indicated for the treatment of the signs and symptoms of dry eye disease.

Xiidra

Xiidra (lifitegrast ophthalmic solution) 5% is indicated for the treatment of the signs and symptoms of dry eye disease (DED).

Coverage Criteria

Dry Eye Disease

Authorization may be granted when the requested drug is being prescribed for the treatment of dry eye disease when the following criteria is met:

- The request is for Cequa, Miebo, Restasis, Tryptyr, Tyrvaya, Vevye, or Xiidra.

Short Term Dry Eye Disease

Authorization may be granted when the requested drug is being prescribed for the treatment of dry eye disease when the following criteria is met:

- The request is for Eysuvis AND the following criteria is met:
 - The requested drug is being prescribed for short-term use (up to two weeks).

Continuation of Therapy

Dry Eye Disease

Authorization may be granted when the requested drug is being prescribed for the treatment of dry eye disease when ALL of the following criteria are met:

- The request is for Cequa, Miebo, Restasis, Tryptyr, Tyrvaya, Vevye, or Xiidra.
- The patient achieved or maintained improvement in their signs and symptoms of dry eye disease from baseline (e.g., ocular irritation, redness, mucous discharge, reduced visual function, ocular surface damage, reduced tear production).

Short Term Dry Eye Disease

All patients (including new patients) requesting authorization for continuation of therapy for Eysuvis must meet ALL requirements in the coverage criteria section.

Quantity Limits Apply

Limits do not accumulate together; patient is allowed the maximum limit for each drug and strength.

The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

The duration of 21 days is used for a 28-day fill period and 63 days is used for an 84-day fill period to allow time for refill processing.

| Drug | 1 Month Limit | 3 Month Limit |
|--|--------------------------------------|---------------------------------------|
| Cequa (cyclosporine ophthalmic solution) | 60 vials / 25 days | 180 vials / 75 days |
| Miebo (perfluorohexyloctane ophthalmic solution) | 1 multi-dose bottle (3 mL) / 25 days | 3 multi-dose bottles (9 mL) / 75 days |

| Drug | 1 Month Limit | 3 Month Limit |
|---|--|---|
| Restasis (cyclosporine ophthalmic emulsion) | 60 vials / 25 days | 180 vials / 75 days |
| Restasis Multidose (cyclosporine ophthalmic emulsion) | 1 multi-dose bottle (5.5 mL) / 21 days | 3 multi-dose bottles (16.5 mL) / 63 days |
| Tryptyr (acoltremon ophthalmic solution) | 60 single-dose vials / 25 days | 180 single-dose vials / 75 days |
| Tyrvaya (varenicline nasal spray solution) | 2 nasal spray bottles (8.4 mL) / 25 days | 6 nasal spray bottles (25.2 mL) / 75 days |
| Vevye (cyclosporine ophthalmic solution) | 1 multi-dose bottle (2 mL) / 25 days | 3 multi-dose bottles (6 mL) / 75 days |
| Xiidra (lifitegrast ophthalmic solution) | 60 containers (1 carton) / 25 days | 180 containers (3 cartons) / 75 days |

These drugs are for short-term acute use.

| Drug | Limit |
|---|-------------------------------|
| Eysuvis (loteprednol etabonate ophthalmic suspension 0.25%) | 2 bottles (16.6 mL) / 90 days |

Duration of Approval (DOA)

- 1955-C:
 - Cequa, Miebo, Restasis, Tryptyr, Tyrvaya, Vevye, Xiidra (Dry eye disease): DOA: 12 months
 - Eysuvis (Short term dry eye disease): DOA: 3 months
- BOG 5484-C
 - Cequa, Miebo, Restasis, Tryptyr, Tyrvaya, Vevye, Xiidra (Dry eye disease): DOA: 12 months (If the request is for Restasis, approve Brand name Restasis)
 - Eysuvis (Short term dry eye disease): DOA: 3 months

References

1. Cequa [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; July 2022.
2. Eysuvis [package insert]. Fort Worth, TX: Alcon Laboratories, Inc.; November 2023.

| Reference number(s) |
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| 1955-C, 5484-C |

3. Miebo [package insert]. Bridgewater, NJ: Bausch & Lomb Americas Inc.; January 2024.
4. Restasis [package insert]. Irvine, CA: Allergan, Inc; September 2024.
5. Restasis Multidose [package insert]. Irvine, CA: Allergan, Inc; September 2024.
6. Tryptyr [package insert]. Fort Worth, TX: Alcon Laboratories, Inc. May 2025.
7. Tyrvaya [package insert]. Princeton, NJ: Oyster Point Pharma, Inc.; September 2024.
8. Vevye [package insert]. Nashville, TN: Harrow Eye, LLC.; November 2023.
9. Xiidra [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; June 2020.
10. Lexicomp Online, AHFS DI (Adult and Pediatric Online. Waltham, MA: UpToDate, Inc.; 2024.
<https://online.lexi.com>. Accessed October 16, 2024.
11. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at:
<https://www.micromedexsolutions.com/> (cited: 10/16/2024).
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13. Pharmacy Auditing and Dispensing Job Aid: Billing Other Dosage Forms. Centers for Medicare and Medicaid Services. December 2015.