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

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
Tyrvaya	varenicline	nasal spray solution
Vevye	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.

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, 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, 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
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, Tyrvaya, Vevye, Xiidra (Dry eye disease): DOA: 12 months
  - Eysuvis (Short term dry eye disease): DOA: 3 months
- BOG 5484-C
  - Cequa, Miebo, Restasis, 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.
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. Tyrvaya [package insert]. Princeton, NJ: Oyster Point Pharma, Inc.; September 2024.
7. Vevye [package insert]. Nashville, TN: Harrow Eye, LLC.; November 2023.
8. Xiidra [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; June 2020.
9. Lexicomp Online, AHFS DI (Adult and Pediatric Online. Waltham, MA: UpToDate, Inc.; 2024. https://online.lexi.com. Accessed October 16, 2024.
10. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 10/16/2024).
11. Akpek EK, Amescua G, Farid M, et al. Dry Eye Syndrome Preferred Practice Pattern. Ophthalmology. 2019;126(1):P286-P334.
12. Pharmacy Auditing and Dispensing Job Aid: Billing Other Dosage Forms. Centers for Medicare and Medicaid Services. December 2015.

Document History

Written by: UM Development (CT)

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CRITERIA FOR APPROVAL

1	Is the requested drug being prescribed for dry eye disease? [If Yes, then go to 2. If No, then no further questions.]	Yes	No

2	Is the request for Cequa, Miebo, Restasis, Tyrvaya, Vevye, or Xiidra? [If Yes, then go to 4. If No, then go to 3.]	Yes	No
3	Is the request for Eysuvis for short-term use (up to 2 weeks)? [If Yes, then go to 7. If No, then no further questions.]	Yes	No
4	Is this request for continuation of therapy? [If Yes, then go to 5. If No, then go to 6.]	Yes	No
5	Has 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)? [If Yes, then go to 6. If No, then no further questions.]	Yes	No
6	Does the patient require MORE than the plan allowance PER MONTH (unless specified otherwise) of any of the following: A) Cequa: 60 vials, B) Miebo: 1 multi-dose bottle (3 mL), C) Restasis: 60 vials OR 1 multi-dose bottle (5.5 mL)/28 days, C) Tyrvaya: 2 nasal spray bottles (8.4 mL), D) Vevye: 1 multi-dose bottle (2 mL), E) Xiidra: 60 containers (1 carton)? [No further questions] RPh Note: If yes, then deny and enter a partial approval per Quantity Limit Chart. (If the request is for Restasis, approve Brand name Restasis.)	Yes	No
7	Does the patient require more than the plan allowance of 2 bottles (16.6mL) per 90 days of Eysuvis? [No further questions] RPh Note: If yes, then deny and enter a partial approval for 2 bottles (16.6 mL) / 90 days of Eysuvis.	Yes	No

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS**
1.	Go to 2	Deny	Your plan only covers this drug when it is used for certain health conditions. Covered use is for dry eye disease. Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing

			information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Diagnosis]
2.	Go to 4	Go to 3	
3.	Go to 7	Deny	Your plan only covers this drug for short-term use (up to two weeks) for your health condition. We have denied your request for this drug because it is for longer treatment. We reviewed the information we had. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Exceeds maximum duration of therapy]
4.	Go to 5	Go to 6	
5.	Go to 6	Deny	Your plan only covers this drug if it works well for you. We have denied your request because the drug did not work well for you. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Continuation: Efficacy]
6.	[Please select appropriate denial close option. For the denial verbiage, only include	[PA Approved for 12 months. (Note: If the request is for Restasis, approve	We have denied your request because it is for more than the amount your plan covers (quantity limit). We reviewed the information we had. We have partially approved your request for this drug up to the amount your plan covers: A) 60 vials per month of Cequa, B) 1 multi-dose bottle per month of Miebo, C) 60 vials per month of Restasis OR 1 multi-dose bottle per 28 days of Restasis, D) 2 nasal spray bottles per month of Tyrvaya, E) 1 multi-dose bottle per month of Vevye, F) 60 containers per month of Xiidra.

	the requested drug. Remove all other drugs from verbiage]. Deny	Brand name Restasis). See Quantity Limit Chart.]. Approve, 12 Months	Your request for more drug has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Quantity, Exceeds max limit, Partial denial]
7.	Deny	[PA Approved for 3 months. Approve Eysuvis: 2 bottles (16.6 mL)/90 days]. Approve, 3 Months	We have denied your request because it is for more than the amount your plan covers (quantity limit). We reviewed the information we had. We have partially approved your request for this drug up to the amount your plan covers (2 bottles per 90 days of Eysuvis). Your request for more drug has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Quantity, Exceeds max limit, Partial denial Eysuvis]