UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2107-17
Program	Prior Authorization – Medical Necessity
Medication	Cequa™ (cyclosporine 0.09% ophthalmic solution)*, Restasis MultiDose® (cyclosporine 0.05% ophthalmic emulsion)*, Tyrvaya™ (varenicline nasal spray), Vevye™ (cyclosporine 0.1%)*
P&T Approval Date	9/2016, 9/2017, 9/2018, 3/2019, 4/2020, 4/2021, 12/2021, 7/2022, 7/2023, 9/2023, 3/2024, 7/2024, 7/2025, 9/2025, 11/2025
Effective Date	2/1/2026

1. Background:

Cequa (cyclosporine 0.09% ophthalmic solution)* and Restasis (cyclosporine 0.05% ophthalmic emulsion)* are indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca.

Miebo® (perfluorohexyloctane), Tryptyr® (acoltremon), Tyrvaya (varenicline nasal spray), Vevye (cyclosporine 0.1%)* and Xiidra® (lifitegrast 5% ophthalmic solution) are indicated for the treatment of the signs and symptoms of dry eye disease.

2. Coverage Criteria [a]:

A. Cequa*, Restasis MultiDose* or Vevye*

1. **Initial Authorization**

a. **Cequa*, Restasis MultiDose* or Vevye*** will be approved based on **all** of the following:

(1) Diagnosis of one of the following:

(a) Moderate to severe keratoconjunctivitis sicca

-OR-

(b) Moderate to severe dry eye disease

-AND-

(2) Not prescribed to manage dry eyes peri-operative elective eye surgery (e.g.: LASIK)

-AND-

(3) History of failure, contraindication or intolerance to **two** of the following:
(a) Miebo

(b) Restasis single dose vials
(c) Tryptyr
(c) Xiidra

-AND-

(4) Medication will not be used in combination with another prescription product for dry eye disease or keratoconjunctivitis sicca (e.g., Miebo, Restasis single dose-vials, Tryptyr, Tyrvaya, Xiidra)

-AND-

(5) Prescribed by or in consultation with **one** of the following:

(a) Ophthalmologist
(b) Optometrist
(c) Rheumatologist

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Cequa*, Restasis MultiDose*, or Vevye*** will be approved based on the following criterion:

(1) Patient has demonstrated clinically significant improvement with therapy

-AND-

(2) Medication will not be used in combination with another prescription product for dry eye disease or keratoconjunctivitis sicca (e.g., Miebo, Restasis single dose-vials, Tryptyr, Tyrvaya, Xiidra)

Authorization will be issued for 12 months.

B. Tyrvaya

1. **Initial Authorization**

a. **Tyrvaya** will be approved based on **all** of the following:

(1) Diagnosis of **one** of the following:

(a) Moderate to severe keratoconjunctivitis sicca

-OR-

(b) Moderate to severe dry eye disease

-AND-

(2) Not prescribed to manage dry eyes peri-operative elective eye surgery (e.g.: LASIK)

-AND-

(3) History of failure, contraindication or intolerance to **two** of the following:

(a) Miebo
(b) Restasis single dose vials
(c) Tryptyr
(d) Xiidra

-AND-

(4) Medication will not be used in combination with another prescription product for dry eye disease or keratoconjunctivitis sicca (e.g., Cequa, Miebo, Restasis, Tryptyr, Vevye, Xiidra)

-AND-

(5) Prescribed by or in consultation with **one** of the following:

(a) Ophthalmologist
(b) Optometrist
(c) Rheumatologist

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Tyrvaya** will be approved based on the following criterion:

(1) Patient has demonstrated clinically significant improvement with therapy

-AND-

(2) Medication will not be used in combination with another prescription product for dry eye disease or keratoconjunctivitis sicca (e.g., Cequa, Miebo, Restasis, Tryptyr, Vevye, Xiidra)

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.

Cequa, Restasis MultiDose and Vevye are typically excluded from coverage.

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
- Prior Authorization – Notification may be in place

4. References:

1. Cequa [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc; December 2022.
2. Miebo [package insert]. Bridgewater, NJ: Bausch & Lomb Americas Inc.; January 2024.
3. Restasis [package insert]. North Chicago, IL: AbbVie Inc.; September 2024.Restasis MultiDose [package insert]. North Chicago, IL: AbbVie Inc.; September 2024.
4. Tryptyr [package insert]. Fort Worth, TX: Alcon Laboratories; May 2025.
5. Tyrvaya [package insert]. Princeton NJ: Oyster Point Pharma, Inc; February 2024
6. Vevye [package insert]. Nashville, TN: Harrow Eye, LLC; November 2023.
7. Xiidra [package insert]. Bridgewater, NJ: Bausch & Lomb Americas Inc; December 2023.
8. American Academy of Ophthalmology. Dry Eye Syndrome Preferred Practice Pattern 2023.

Program	Prior Authorization – Medical Necessity – Dry Eye Disease
Change Control	
9/2016	New program.
11/2016	Administrative change. Added California coverage information.
9/2017	Annual review. Administrative updates. Added Restasis MultiDose. Updated references.
9/2018	Annual review. Administrative updates and updated references.
12/2018	Administrative change to add statement regarding use of automated processes.
3/2019	Added Cequa and updated references.
4/2020	Annual review. Added a step through Restasis single use vials for Cequa and Restasis MultiDose. Updated references.
4/2021	Annual review. Updated references.
12/2021	Added Tyrvava.
7/2022	Removed Restasis single dose vials and Xiidra from the criteria.
7/2023	Annual review. Added step through Xiidra for Cequa & Restasis Multidose. Updated references.
9/2023	Added Miebo and Vevye.
3/2024	Updated the initial authorization to 12 months. Updated references.
7/2024	Removed Miebo from Medical Necessity criteria. Added language on concomitant therapy. Removed referenced to compound Notification.
7/2025	Annual review. Updated diagnosis language. Updated references.
9/2025	Removed OTC step and added Miebo as an option. Updated references.
11/2025	Added Tryptyr as a step 1 option.