UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 2107-12
Program	Prior Authorization – Medical Necessity
Medication	Cequa™ (cyclosporine 0.09% ophthalmic solution)*, Miebo™ (perfluorohexyloctane)*, 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
Effective Date	12/1/2023

1. Background:

Cequa (cyclosporine 0.09% ophthalmic solution)* and Restasis MultiDose (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)*, 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*, Miebo*, Restasis MultiDose* or Veyve*

1. **Initial Authorization**

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

(1) Tear deficiency associated with ocular inflammation due to **one** of the following:

(a) Moderate to severe keratoconjuctivitis 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 to at least one OTC artificial tear product (e.g., Systane® Ultra, Akwa® Tears, Refresh Optive®, Soothe® XP)

-AND-

(4) History of failure, contraindication or intolerance to **both** of the following:
(a) Restasis single dose vials
(b) Xiidra

-AND-

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

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

Authorization will be issued for 6 months.

2. **Reauthorization**

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

(1) Patient has demonstrated clinically significant improvement with therapy

Authorization will be issued for 12 months.

B. Tyrvava

1. **Initial Authorization**

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

(1) Tear deficiency associated with ocular inflammation due to **one** of the following:

(a) Moderate to severe keratoconjuctivitis 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 to at least one OTC artificial tear product (e.g., Systane® Ultra, Akwa® Tears, Refresh Optive®, Soothe® XP)

-AND-

(4) History of failure, contraindication or intolerance to **both** of the following:

(a) Restasis single dose vials
(b) Xiidra

-AND-

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

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

Authorization will be issued for 6 months.

2. **Reauthorization**

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

(1) Patient has demonstrated clinically significant improvement with therapy

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, Miebo, 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
- Compound and Bulk powder 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; May 2023.
3. Restasis [package insert]. Irvine, CA: Allergan, Inc.; July 2017.
4. Restasis MultiDose [package insert]. Irvine, CA: Allergan, Inc.; October 2016.
5. Tyrvaya [package insert]. Princeton NJ: Oyster Point Pharma, Inc; October 2021.
6. Vevye [package insert]. Irvine CA: Alliance Medical Products, Inc; June 2023.
7. Xiidra [package insert]. Hanover, NJ: Novartis Pharmaceuticals Corporation: June 2020.
8. American Academy of Ophthalmology. Dry Eye Syndrome Preferred Practice Pattern 2018.

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.