UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 1088-16
Program	Prior Authorization-Notification
Medication	Cequa™ (cyclosporine 0.09% ophthalmic solution)*, Miebo™ (perfluorohexyloctane), Restasis® (cyclosporine 0.05% ophthalmic emulsion), Restasis MultiDose™ (cyclosporine 0.05% ophthalmic emulsion)*, Tyrvaya™ (varenicline nasal spray), Vevye™ (cyclosporine 0.1%)*, Xiidra® (lifitegrast 5% ophthalmic solution)
P&T Approval Date	3/2006, 3/2007, 8/2008, 8/2009, 9/2010, 3/2011, 2/2012, 2/2013, 4/2014, 4/2015, 3/2016, 12/2016, 9/2017, 9/2018, 3/2019, 4/2020, 4/2021, 12/2021, 12/2022, 9/2023, 3/2024, 7/2024
Effective Date	8/18/2024

1. Background:

Cequa (cyclosporine 0.09% ophthalmic solution)*, Restasis (cyclosporine 0.05% ophthalmic emulsion) 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. <u>Initial Authorization</u>

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

   a. Diagnosis of **<u>one</u>** of the following:

      1) Moderate to severe keratoconjunctivitis sicca
      2) Dry Eye Disease

-AND-

   b. Medication will not be used in combination with another prescription product for dry eye disease or keratoconjunctivitis sicca

Authorization will be issued for 12 months.

B. <u>Reauthorization</u>

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

   a. Patient has demonstrated clinically significant improvement with therapy

-AND-

b. Medication will not be used in combination with another prescription product for dry eye disease or keratoconjuctivitis sicca

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 Vevyeare 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 – Medical Necessity 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; 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.
6. American Academy of Ophthalmology. Dry Eye Syndrome Preferred Practice Pattern 2023.

Program	Notification – Dry Eye Disease
Change Control	
4/2014	No changes to criteria. Updated references.
4/2015	Updating authorization criteria to 6 months and reauthorization criteria to 12 months to align with prior authorization-medical necessity criteria
3/2016	Removed the Prior Authorization-Medical Necessity program language.
12/2016	Updated criteria to allow for Dry Eye Disease. Added Xiidra to criteria. Changed name of criteria to Dry Eye Disease.
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. Removed extemporaneously compounded cyclosporine criteria. Updated references.
4/2021	Annual review. Updated references.
12/2021	Added Tyrvaya.

12/2022	Annual review. Added state mandate language. Updated references.
9/2023	Added Miebo and Vevye. Updated references.
3/2024	Updated initial authorization to 12 months. Updated references.
7/2024	Added concomitant therapy language. Updated references.