UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2021 1088-12
Program	Prior Authorization-Notification
Medication	Cequa™ (cyclosporine 0.09% ophthalmic solution)*, Restasis® (cyclosporine 0.05% ophthalmic emulsion), Restasis MultiDose (cyclosporine 0.05% ophthalmic emulsion)*, Tyrvaya™ (varenicline nasal spray), 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
Effective Date	3/1/2022; Oxford only: N/A

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.
Tyrvaya™ (varenicline nasal spray) and Xiidra™ (lifitegrast 5% ophthalmic solution) are indicated for the treatment of the signs and symptoms of dry eye disease.

2. Coverage Criteria:

A. Initial Authorization

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

   a. Diagnosis of **one** of the following:

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

   Authorization will be issued for 6 months.

B. Reauthorization

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

   a. Patient has demonstrated clinically significant improvement with therapy

   Authorization will be issued for 12 months.

*Cequa and Restasis MultiDose 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 – Medical Necessity may be in place.

4. References:

1. Cequa [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc; January 2021.
2. Restasis [package insert]. Irvine CA: Allergan, Inc.: July 2017.
3. Restasis MultiDose [package insert]. Irvine, CA: Allergan, Inc.; October 2016.
4. Tyrvaya [package insert]. Princeton NJ: Oyster Point Pharma, Inc; October 2021.
5. Xiidra [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; June 2020.
5. American Academy of Ophthalmology. Dry Eye Syndrome Preferred Practice Pattern 2018. Accessed March 1, 2021.

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.