PRIOR AUTHORIZATION CRITERIA

BRAND NAME*
(generic)

CEQUA
(cyclosporine ophthalmic solution)

RESTASIS
(cyclosporine ophthalmic emulsion)

Status: CVS Caremark Criteria ***Ref # 704-C***
Type: Initial Prior Authorization with Quantity Limit ***Ref # MMT 1220-C***

** Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated. OTC products are not included unless otherwise stated.*

FDA-APPROVED INDICATION

Cequa
Cequa ophthalmic solution is a calcineurin inhibitor immunosuppressant indicated to increase tear production in patients with keratoconjunctivitis sicca (dry eye).

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.

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug is being prescribed for dry eye disease
  AND
- The patient has experienced an inadequate treatment response to an artificial tears product
  OR
- The patient has experienced an intolerance to an artificial tears product
  OR
- The patient has a contraindication that would prohibit a trial of an artificial tears product

Quantity Limits apply.

RATIONALE

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Cequa ophthalmic solution is a calcineurin inhibitor immunosuppressant indicated to increase tear production in patients with keratoconjunctivitis sicca (dry eye). 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.[1-5]

The Preferred Practice Pattern (PPP) for Dry Eye Syndrome by the American Academy of Ophthalmology classifies dry eye as mild, moderate, and severe based on both symptoms and signs, but with an emphasis on symptoms over signs. The PPP notes that this classification is imprecise because characteristics at each level overlap due to the nature of dry eye disease. Dry eye syndrome is also categorized into one of two forms, aqueous tear deficiency and evaporative dry eye, which coexist in the majority of patients with the disease. Ocular lubricants, such as artificial tear substitutes, are a

Step-1 treatment option for dry eye. Artificial tear substitutes have been found to be a safe and effective treatment for dry eye. Topical cyclosporine is a Step-2 treatment option.[6] Therefore, coverage for Cequa or Restasis will be provided for patients with dry eye disease who have experienced an inadequate treatment response or intolerance to, or who have a contraindication that would prohibit a trial of an artificial tears product.

Dosage for Cequa and Restasis is one drop in each eye twice a day, 4 drops per day total. Cequa and Restasis are available as single-use vials. Each vial contains enough solution or emulsion to deliver one drop in each eye.[1,2] Therefore, the limit for Cequa and Restasis vials will be set at 60 vials per month.

Restasis is also available as a 5.5 mL multi-dose bottle.[3] According to the Centers for Medicare and Medicaid Services, it is appropriate to use a conversion factor of 20 drops per mL to calculate a days' supply.[7] Using this conversion, there are 110 drops per multi-dose bottle of Restasis. After priming the bottle for first time use by squeezing out 2 drops, 108 drops remain, and at 4 drops per day, this equates to a 27 day supply. Therefore, the limit for Restasis multi-dose bottle will be set at 1 bottle per month.

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. Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Hudson, Ohio: UpToDate, Inc.; 2021; Accessed Month Day, Year.
5. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com. Accessed Month Day, Year.
6. Preferred Practice Pattern. Dry Eye Syndrome. American Academy of Ophthalmology. November 2018.
7. Pharmacy Auditing and Dispensing Job Aid: Billing Other Dosage Forms. Centers for Medicare and Medicaid Services. December 2015.

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CRITERIA FOR APPROVAL

1	Is the requested drug being prescribed for dry eye disease? [If no, then no further questions.]	Yes	No
2	Has the patient experienced an inadequate treatment response to an artificial tears product? [If yes, then skip to question 5.]	Yes	No
3	Has the patient experienced an intolerance to an artificial tears product? [If yes, then skip to question 5.]	Yes	No
4	Does the patient have a contraindication that would prohibit a trial of an artificial tears product? [If no, then no further questions.]	Yes	No

5	Does the patient require more than the plan allowance of 4 drops per day of the requested drug? [RPh Note: If yes, then deny and enter a partial approval per Quantity Limit Chart.]	Yes	No

Mapping Instructions (704-C)			
	Yes	**No**	**DENIAL REASONS – DO NOT USE FOR MEDICARE PART D**
1.	Go to 2	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you have dry eye disease. Your request has been denied based on the information we have. [Short Description: No approvable diagnosis]
2.	Go to 5	Go to 3	
3.	Go to 5	Go to 4	
4.	Go to 5	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you have tried an artificial tears product and it either did not work for you or you cannot use it. Your request has been denied based on the information we have. [Short Description: No inadequate response, intolerance or contraindication to artificial tears]
5.	Deny RPh Note: For the denial verbiage, only include the requested drug. Remove all the other drugs from the verbiage.	Approve, 36 months, See Quantity Limit Chart	You have requested more than the maximum quantity allowed by your plan. Current plan approved criteria cover up to: - 60 vials per month of Cequa - 60 vials per month of Restasis - 1 multi-dose bottle per month of Restasis Your request has been partially approved. You have been approved for the maximum quantity that your plan covers for a duration of 36 months. Your request for additional quantities of the requested drug and strength has been denied. [Short Description: Over max quantity]

Mapping Instructions (MMT 1220-C)			
	Yes	**No**	**DENIAL REASONS – DO NOT USE FOR MEDICARE PART D**
1.	Go to 2	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you have dry eye disease. Your request has been denied based on the information we have. [Short Description: No approvable diagnosis]
2.	Go to 5	Go to 3	
3.	Go to 5	Go to 4	
4.	Go to 5	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you have tried an artificial tears product and it either did not work for you or you cannot use it. Your request has been denied based on the information we have. [Short Description: No inadequate response, intolerance or

			contraindication to artificial tears]
5.	Deny RPh Note: For the denial verbiage, only include the requested drug. Remove all the other drugs from the verbiage.	Approve, 12 months, See Quantity Limit Chart	You have requested more than the maximum quantity allowed by your plan. Current plan approved criteria cover up to: - 60 vials per month of Cequa - 60 vials per month of Restasis - 1 multi-dose bottle per month of Restasis Your request has been partially approved. You have been approved for the maximum quantity that your plan covers for a duration of 12 months. Your request for additional quantities of the requested drug and strength has been denied. [Short Description: Over max quantity]

QUANTITY LIMIT

Drug	**1 Month Limit***	**3 Month Limit***
Cequa vials	60 vials / 25 days	180 vials / 75 days
Restasis vials	60 vials / 25 days	180 vials / 75 days
Restasis multi-dose bottle	1 bottle / 21 days	3 bottles / 63 days

**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.*