MEDICAL MUTUAL®

Drug Policy

Policy:	Cequa 0.09% (cyclosporine opthalmic solution)	Annual Review Date: 04/20/2023 Last Revised Date: 04/20/2023

OVERVIEW

Cequa is a topical solution containing cyclosporine, a calcineurin inhibitor immunosuppressant when administered systemically. Topical administration of cyclosporine is thought to act as a partial immunomodulator, but the exact mechanism of action is unknown. Cequa is indicated to increase tear production in patients with keratoconjunctivitis sicca (dry eye).

POLICY STATEMENT

This policy involves the use of Cequa. Prior authorization is recommended for pharmacy benefit coverage of Cequa. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Cequa as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Cequa be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Cequa is recommended in those who meet the following criteria:

1. **Keratoconjunctivitis Sicca (Dry Eye Syndrome)**
   Criteria. *Patient must meet the following criteria (A, B, C, and D):*
   - A. Patient is 18 years of age or older; AND
   - B. Cequa is prescribed by or in consultation with an ophthalmologist, optometrist, or rheumatologist; AND
   - C. The provider has administered testing for one of the following homeostasis markers with corresponding results [documentation in medical chart records required] (a, b, c, or d):
     - a. Schirmer's test (< 5 mm of wetting over 5 minutes), OR
     - b. Non-invasive tear breakup time (< 10 s), OR
     - c. Osmolarity (≥ 308 mOsm/L in either eye or interocular difference of > 8 mOsm/L), OR

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d. Ocular surface staining (> 5 corneal spots, > 9 conjucntival spots, or lid margin [≥ 2 mm length and ≥ 25% width]); AND

D. If the diagnosis is mild dry eye disease, the patient has tried and failed on preservative free artificial tears

2. Keratoconjunctivitis Sicca (Dry Eye Syndrome), Continuation of Therapy.
Criteria. *Patient must meet the following criteria (A, B, and C)*

A. The patient is 18 years of age or older; AND
B. The medication is prescribed by or in consultation with an ophthalmologist, optometrist, or rheumatologist; AND
C. The patient has had a beneficial response to therapy, including reduced eye irritation, dryness, red eyes, or burning).

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

Other Uses with Supportive Evidence

1. Dry Eye Conditions due to Systemic Inflammatory Disease (e.g. Sjogren's Syndrome, rheumatoid arthritis [RA], Systemic Lupus Erythematosus [SLE]).
Criteria. *Patient must meet the following criteria*

A. The patient is 18 years of age or older; AND
B. The medication is prescribed by an ophthalmologist, optometrist or rheumatologist.

2. Dry Eye Conditions due to Ocular Surface Diseases (e.g., ocular rosacea, atopic keratoconjunctivitis, acute corneal graft rejection, blepharitis, herpetic stromal keratitis, conjunctival graft versus host disease).
Criteria. *Patient must meet the following criteria*

A. The patient is 18 years of age or older; AND
B. The medication is prescribed by an ophthalmologist, optometrist or rheumatologist.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Cequa has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. **Concomitant use with Restasis, Verkazia, or Xiidra.** There is no evidence to support the concomitant use of Cequa with Restasis or Xiidra. Cequa contains the same active ingredient as Restasis.

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2. **Management of dry eyes peri-operative elective eye surgery** (e.g. LASIK).

3. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Cequa [prescribing information]. Cranbury, NJ: Sun Pharmaceutical Industries; August 2018.
2. American Academy of Ophthalmology cornea/external disease panel. Preferred practice pattern® guidelines. Dry eye syndrome. San Francisco, CA: American Academy of Ophthalmology; 2018. Available at: www.aao.org/ppp. Accessed on 12 September 2019.
3. Cyclosporine. In: DRUGDEX [online database]. Truven Health Analytics. Greenwood Village, CO. Last updated 28 August 2019. Accessed 12 September 2019.

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