MEDICAL MUTUAL®

Drug Policy

Policy:	**Restasis 0.05% (cyclosporine ophthalmic emulsion – Allergan, generics)*** **Restasis MultiDose 0.05% (cyclosporine ophthalmic emulsion – Allergan)**	**Annual Review Date:** **04/18/2024** **Last Revised Date:** **04/18/2024**

OVERVIEW

Restasis is a topical emulsion which contains cyclosporine, an immunosuppressive agent when administered systemically. It also has anti-inflammatory effects with some evidence suggesting that it is a disease-modifying agent rather than being a merely palliative treatment for dry eye syndrome. Restasis is indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca (KCS). Increased tear production was not seen in patients currently taking topical anti-inflammatory drugs or using punctal plugs. Though its exact mechanism to alleviate ocular inflammation and to increase tear production is unknown, it is thought to act as a partial immunomodulator. The safety and efficacy of Restasis have not been established in pediatric patients < 16 years of age.

POLICY STATEMENT

This policy involves the use of Restasis. Prior authorization is recommended for pharmacy benefit coverage of Restasis. 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 Restasis as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Restasis 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.

*Note: Restasis (with DAW9) is subject to brand-for-generic substitution.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indication

1. **Dry Eye Conditions due to Ocular Inflammation Associated with Keratoconjunctivitis Sicca (e.g. dry eye syndrome or dry eye disease), Initial Use.**
   Criteria. *Patient must meet the following criteria*

A. The patient is 16 years of age or older; AND
B. The medication 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 (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
    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. Dry Eye Conditions due to Ocular Inflammation Associated with Keratoconjunctivitis Sicca (e.g. dry eye syndrome or dry eye disease), Continuation of Therapy.
Criteria. *Patient must meet the following criteria*

A. The patient is 16 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

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3. 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 16 years of age or older; AND
B. The medication is prescribed by an ophthalmologist, optometrist or rheumatologist.

4. 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 16 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

Restasis 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 Another Ophthalmic Cyclosporine Product, Miebo (perfluorohexyloctane ophthalmic solution), Tyrvaya (varenicline nasal solution), or Xiidra (lifitegrast ophthalmic solution).** There are no data to support the concomitant use of two (or three) ophthalmic cyclosporine products or the concomitant use of an ophthalmic cyclosporine product with Miebo, Tyrvaya, or Xiidra.
   Note: Ophthalmic cyclosporine products are Cequa, Restasis, and Vevye.

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

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