Clinical Policy: Cyclosporine Ophthalmic Emulsion (Restasis)

Reference Number: CP.CPA.146
Effective Date: 11.16.16
Last Review Date: 11.16 Revision Log
Line of Business: Medicaid – Medi-Cal

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Cyclosporine ophthalmic emulsion (Restasis®) contains a topical immunomodulator with anti-inflammatory effects.

FDA approved indication
Restasis is indicated for the treatment to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca.

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with Centene Corporation® that Restasis is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Keratoconjunctivitis Sicca (must meet all)**:**

1. Diagnosis of moderate to severe keratoconjunctivitis sicca (chronic dry eye disease (CDED));
2. Prescribed by or in consultation with an ophthalmologist or optometrist;
3. Failure of any non-prescription wetting agents in the form of drops, ointments, or gels unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed 2 drops/day in each eye.

Approval duration: Length of Benefit

B. Other diagnoses/indications

1. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

II. Continued Therapy

A. Keratoconjunctivitis Sicca (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Documentation of positive response to therapy;
3. Dose does not exceed 2 drops/day in affected eye.

Approval duration: Length of Benefit

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.PMN.53 or evidence of coverage documents

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
CDED: chronic dry eye disease

Appendix B: General Information
- Artificial tears are the standard therapy for all severity of dry eyes.
- Restasis is likely to be given in conjunction with artificial tears.
- Increased tear production was not seen in patients currently taking topical anti-inflammatory drugs or using punctal plugs.
- Emulsion from one individual single-use vial is to be used immediately after opening for administration to one or both eyes, and the remaining contents should be discarded immediately after administration.

Appendix C: Therapeutic Alternatives

Drug	Dosing Regimen	Dose Limit/Maximum Dose
Various OTC products	1-2 drops in affected eye(s) TID or QID	N/A

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Moderate to severe keratoconjunctivitis sicca (chronic dry eye disease (CDED))	1 drop BID in each eye approximately 12 hours apart	2 drops/day in each eye

VI. Product Availability

Single use vial: 0.05%, 0.4 ml each of 30 vials/tray and 60 vials/tray

VII. References

1. Restasis. Drug Monograph. Clinical Pharmacology. Accessed January 12, 2017. http://www.clinicalpharmacology-ip.com
2. Restasis. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed January 12, 2017.
3. Restasis Prescribing Information. Irvine, CA: Allergan, Inc; June 2013. Available at http://www.allergan.com/assets/pdf/restasis_pi.pdf. Accessed on January 12, 2017.
4. Sall K, Stevenson OD, Mundorf TK, et al for the CsA Phase 3 Study Group. Ophthalmic emulsion in moderate to severe dry eye disease. *Ophthalmology* 2000;107:631-639.
5. Restasis. American Hospital Formulary Service Drug Information. Available at: http://www.medicinescomplete.com/mc/ahfs/current/. Accessed January 12, 2017.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Converted to new template. Minor changes to verbiage and grammar. References updated.	01.19.17	11.17

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right

to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.