Clinical Policy: Cyclosporine (Restasis)
Reference Number: CP.PMN.48
Effective Date: 05/12
Last Review Date: 05/17
Line of Business: Medicaid

Coding Implications
Revision Log

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

Description
Cyclosporine (Restasis®) is a topical immunomodulator.

FDA approved indication
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. Increased tear production was not seen in patients currently taking topical anti-inflammatory drugs or using punctal plugs.

Policy/Criteria
Provider must submit documentation (including 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 ~~s~~Sicca (must meet all)**:**

1. Diagnosis of keratoconjunctivitis sicca with suppressed tear production due to ocular inflammation;
~~2. Age ≥ 16 years;~~
~~3.~~2. Failure of a ≥ 2 month trial of artificial tears at up to maximally indicated doses ~~for ≥ 2 months~~ unless ~~member experiences clinically significant adverse effects or has contraindication(s)~~contraindicated or clinically significant adverse effects are experienced;
~~4.~~3. Failure of ophthalmic anti-inflammatory agents at up to maximally indicated doses~~,~~ unless contraindicated or clinically significant adverse effects are experienced~~member experiences clinically significant adverse effects or has contraindication(s)~~;
~~5.~~4. Dose does not exceed FDA approved maximum recommended dose (60 vials/ 30~~month~~ days).

Approval duration: 6 months

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 S~~s~~icca (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. If request is for a dose increase, new dose does not exceed FDA approved maximum recommended dose (60 vials/~~month~~30 days).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy; or
2. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

Approval duration: 12 months

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
FDA: Food & Drug Administration

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Keratoconjunctivitis sicca	1 drop twice daily in each eye	1 drop twice daily in each eye

VI. Product Availability

Ophthalmic emulsion: 0.5 mg/mL

VII. Workflow Document

Restasis WF.docx

Field Code Changed

VIII. References

~~1. Shtein RM. Dry eyes. Trobe J, Park L. (Ed), UpToDate. Waltham MA. Accessed February 8, 2016.~~

~~2.~~1. Restasis® ~~p~~Prescribing ~~I~~information. Irvine, CA: Allergan, Inc.; June 2013. Available at: https://www.restasis.com/. Accessed ~~February 8, 2016~~January 2017.

~~3.~~ The International Dry Eye Workshop. Ocul Surf. 2007; 5(2):65-204. ~~Accessed April 2013.~~
~~4.~~2. ~~Moss SE, Klein R, Klein BE. Prevalence of and risk factors for dry eye syndrome. Arch Ophthalmol. 2000; 118(9):1264-1268. Accessed April, 2013.~~
~~5.~~3. American Academy of Ophthalmology Retina Panel. Preferred Practice Pattern® Guidelines. Dry Eye Syndrome. San Francisco, CA: American Academy of Ophthalmology; October, 2013. Available at: www.aao.org/ppp.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Removed "for a period of 3 months" related to ophthalmic anti-inflammatory use in the Criteria for Approval item D.	05/13	05/13
Updated references.	05/14	05/14
Updated references.	04/15	04/15
Converted to new template; Removed requirement of "failure of environmental stress reduction (use of humidifiers; consciously attempting to increase the frequency of blinking; washing the lids with a mild soap solution; and application of warm compresses)"; Updated references.	02/16	05/16
~~No clinical changes to criteria:~~ - Converted to new template - Removed age criteria as age is not an absolute contraindication per FDA labeling - Updated references	03~~1~~/17	05/17

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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.