Pharmacy Medical Necessity Guidelines: Medications for Dry Eye Disease

Effective: November 10, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM

These pharmacy medical necessity guidelines apply to the following:
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:
RXUM: 617.673.0939

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Restasis (cyclosporine A) is a calcineurin immunomodulator indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with KCS. Increased tear production was not seen in patients currently taking topical anti-inflammatory drugs or using punctal plugs.

Cequa (cyclosporine) 0.09% is approved to increase tear production in patients with keratoconjunctivitis sicca. Cequa is packaged in sterile, preservative-free, single-use vials.

Dry eye disease (DED), otherwise known as keratoconjunctivitis sicca (KCS), is an ocular condition that occurs when the eye does not produce tears properly, or tears evaporate too quickly due to incorrect consistency. The condition can be caused by many factors that result in the inflammation of the eye and tear producing glands. Inflammation can decrease tear production and therefore decrease the protection and lubrication tears provide. Common symptoms of DED include chronic eye dryness, pain and redness of the eye, and stinging or burning of the eye.

COVERAGE GUIDELINES

Restasis (cyclosporine) and Cequa (cyclosporine)

The plan may authorize coverage of Restasis (cyclosporine) for Members, when **ALL** of the following criteria are met:

1. The member is the minimum age studied for the requested product:
    a. **Restasis:** member is 16 years of age or older
    b. **Cequa:** member is 18 years of age or older

AND

2. The Member has had an inadequate response, adverse reaction, or contraindication to at least two separate 30-day trials using two different over-the-counter ocular lubricants/artificial tear solutions during each trial

AND

3. **Cequa only:** The Member has had an inadequate response, adverse reaction, or contraindication to cyclosporine 0.05% (generic Restasis)

LIMITATIONS

1. Requests for brand-name products, which have AB-rated generics, will be reviewed according to the Non-covered Medications criteria.

CODES

None

REFERENCES

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13. Semba CP, Torkildsen GL, Lonsdale JD, et al. A phase 2 randomized, double-masked, placebo-controlled study of novel integrin antagonist (SAR 1118) for the treatment of dry eye. *Am J Opthalmol*. 2012;153(6):1050-60.
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APPROVAL HISTORY

October 11, 2022: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. November 14, 2023: Updated Pharmacy Utilization Management fax number. Effective February 1, 2024, removed diagnosis and prescriber requirements. Updated the criteria for Cequa to require a trial with generic Restasis.
2. November 12, 2024: No changes
3. November 4, 2025: No changes
4. November 10, 2026: No changes.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.