Pharmacy Medical Necessity Guidelines: Medications for Dry Eye Disease

Effective: January 12, 2021

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:

Commercial Products

☐ Tufts Health Plan Commercial products – large group plans
☐ Tufts Health Plan Commercial products – small group and individual plans
☐ Tufts Health Freedom Plan products – large group plans
☐ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:
RXUM: 617.673.0988

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 topical immunomodulator 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.

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.

Sjogren's syndrome is a chronic disease in which white blood cells attack the moisture-producing glands. It is a systemic disease with symptoms of dry eyes and dry mouth, but it affects many organs and may cause fatigue.

Restasis (cyclosporine A) helps to reduce inflammation attributed to DED.

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.

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 prescribing physician is an ophthalmologist or optometrist

AND

3. The Member has at least one of the following documented diagnoses:
    a. Definite diagnosis of Sjögren's Syndrome
    b. Member is being treated for Ocular Graft vs. Host Disease or Corneal Transplant Rejection
    c. Definite diagnosis of chronic dry eye disease
    d. Definite diagnosis of keratoconjunctivitis sicca
    e. Definite diagnosis of keratitis sicca
    f. Definite diagnosis of xerophthalmia

AND

4. The Member has failed at least two separate 30-day trials using two different over-the-counter ocular lubricants/artificial tear solutions during each trial

LIMITATIONS

1. Restasis (cyclosporine A) has a quantity limit of 60 units per 30 days.
2. Cequa (cyclosporine) has a quantity limit of 60 units per 30 days.

CODES

None

REFERENCES

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4. Brown MM, Brown GC, Brown HC, et al. Value-based medicine, comparative effectiveness, and cost-effectiveness analysis of topical cyclosporine for the treatment of dry eye syndrome. *Arch Ophthalmol*. 2009 Feb;127(2):146-52.
5. Cequa (cyclosporine) [prescribing information]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; September 2019.
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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.
14. Sheppard JD, Torkildsen GL, Lonsdale JD, et al. Lifitegrast ophthalmic solution 5.0% for treatment of DED: results of the OPUS-1 phase 3 study. *Ophthalmology*. 2014;121(2):475-83.
15. Tauber J, Karpecki P, Latkany R, et al. Lifitegrast ophthalmic solution 5.0% versus placebo for treatment of dry eye disease: results of the randomized phase III OPUS-2 study. *Ophthalmology*. 2015;122(12):2423-31.

APPROVAL HISTORY

November 2003: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. November 9, 2004: No changes.

2. October 11, 2005: No changes.
3. November 8, 2005: Add to criteria #2a, the requirement of a definitive diagnosis of Keratoconjuctivitis Sicca (KCS) by an ophthalmologist or an optometrist
4. September 12, 2006: No changes
5. September 11, 2007: Changed criteria #1 from requiring "failure of an artificial tears product AND a lubricant eye ointment INCLUDING the vehicle used in Restasis that is commercially available as Refresh Endura" to requiring failure of Refresh Endura AND either a lubricant eye ointment or a lubricant eye gel. Updated attached list with currently available examples of lubricant eye ointment and lubricant eye gel products.
6. January 15, 2008: Added new product reformulation, "Refresh Dry Eye Therapy SensitiveTM" to criteria #1
7. January 13, 2009: No changes
8. May 12, 2009: Removed failure of Refresh Endura™ Lubricant Eye Drops or Refresh Dry Eye Therapy Sensitive™ from criteria and changed prerequisite requirement to two OTC ocular lubricants used in combination with an artificial tears agent. Removed requirement of treatment with a lubricant from diagnosis of Sjögren's Syndrome. Added Ocular Graft vs. Host Disease and Corneal Transplant Rejection to coverage guidelines.
9. January 1, 2010: Removal of Tufts Medicare Preferred language (separate criteria have been created specifically for Tufts Medicare Preferred).
10. May 11, 2010: No changes
11. May 10, 2011: No changes
12. February 14, 2012: No changes
13. September 11, 2012: Updated list of examples of artificial tear solutions and ocular lubricants. Changed requirement of failure of at least two OTC ocular lubricants used in combination with an artificial tears agent to failure of at least two separate 30-day trials using two different OTC ocular lubricants / artificial tear solutions during each trial.
14. July 9, 2013: No changes.
15. September 10, 2013: Clarified criteria 3a to include Chronic Dry Eye Syndrome, Keratitis Sicca, and Xerophthalmia.
16. September 9, 2014: No changes.
17. September 16, 2015: No changes.
18. January 1, 2016: Administrative change to rebranded template applicable to Tufts Health Direct.
19. June 14, 2016: No changes. Effective June 20, 2016, Medical Necessity Guideline applies to Tufts Health Together.
20. November 15, 2016: Changed the name of the Medical Necessity Guideline from "Restasis® (cyclosporine A)" to "Medications for Dry Eye Disease." Added approval criteria for Xiidra (lifitegrast).
21. April 11, 2017: Administrative update, Adding Tufts Health RITogether to the template.
22. November 14, 2017: Administrative update. Removed other lines of business from Medical Necessity Guideline and removed references to Xiidra.
23. December 11, 2018: Administrative changes made to template.
24. October 15, 2019: Administrative update; removed examples of ocular lubricants from the MNG.
25. January 14, 2020: Added Cequa (cyclosporine) to the Medical Necessity Guideline.
26. January 12, 2021: 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.