Pharmacy Medical Necessity Guidelines:
Medications for Dry Eye Disease

Effective: November 20, 2017

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This Pharmacy Medical Necessity Guideline applies to the following:

**Tufts Health Plan Commercial Plans**
- ✓ Tufts Health Plan Commercial Plans – large group plans
- ✓ Tufts Health Plan Commercial Plans – small group and individual plans

**Tufts Health Public Plans**
- ✓ Tufts Health Direct – Health Connector
- ✓ Tufts Health Together – A MassHealth Plan
- □ Tufts Health RITogether – A Rite Care + Rhody Health Partners Plan

**Tufts Health Freedom Plan products**
- ✓ Tufts Health Freedom Plan – large group plans
- ✓ Tufts Health Freedom Plan – small group plans

Fax Numbers:

| RXUM: 617.673.0988 |

**Note:** For Tufts Health Plan Medicare Preferred Members, please refer to the Tufts Health Plan Medicare Preferred Prior Authorization Criteria. Background, applicable product and disclaimer information can be found on the last page.

**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 punctual plugs.

Xiidra (lifitegrast) is a lymphocyte function-associated antigen-1 antagonist indicated for the treatment of the signs and symptoms of dry eye disease (DED).

**COVERAGE GUIDELINES**

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

1. The member is 16 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

**Xiidra (lifitegrast)**
The plan may authorize coverage of Xiidra (lifitegrast) for Members, when all of the following criteria are met:

1. The Member is 17 years of age or older
2. The prescribing physician is an ophthalmologist or optometrist

3. The Member has a definite diagnosis of dry eye disease

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

**ATTACHMENT**

Examples of artificial tear solutions and ocular lubricants:

**Alcon (preservative free)**
- Systane® Nighttime Lubricant Eye Ointment
- Tears Naturale® P.M. Lubricant Eye Ointment

**Altaire**
- Tears Again® Lubricant Eye Ointment

**Ocusoft**
- Retaine MGD® Lubricant Eye Emulsion (preservative free)
- Tears Again® Night & Day Lubricant Eye Gel
- Tears Again® Advanced Lubricant Eye Spray

**Fera Pharmaceuticals**
- Puralube® Lubricant Eye Ointment

**Allergan Optical**
- Refresh® Lacri-Lube® Lubricant Eye Ointment

**Allergan (preservative free)**
- Refresh PM® Lubricant Eye Ointment

**Rugby**
- Artificial Tears® Lubricant Eye Ointment

**Bausch & Lomb (preservative free)**
- Dry Eyes® Lubricant Eye Ointment
- Soothe® Night Time Lubricant Eye Ointment

**Novartis Ophthalmics (preservative free)**
- HypoTears® Lubricant Eye Ointment

**Del Pharm**
- Stye® Lubricant Eye Ointment

**Major (preservative free)**
- LubriFresh P.M.® Lubricant Eye Ointment

**Abbott**
- Blink Gel® Tears Lubricating Eye Drops Lubricant Eye Gel

**Novartis**
- GenTeal® PM Lubricant Eye Ointment
- GenTeal® Severe Eye Relief Lubricant Eye Ointment (preservative free)

**LIMITATIONS**

None

**CODES**

None

**REFERENCES**


APPRAVAL HISTORY

November 2003: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
- November 9, 2004: No changes.
- October 11, 2005: No changes.
- November 8, 2005: Add to criteria #2a, the requirement of a definitive diagnosis of Keratoconjunctivitis Sicca (KCS) by an ophthalmologist or an optometrist
- September 12, 2006: No changes
- 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.
- January 15, 2008: Added new product reformulation, “Refresh Dry Eye Therapy Sensitive™” to criteria #1
- January 13, 2009: No changes
- 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.
- January 1, 2010: Removal of Tufts Medicare Preferred language (separate criteria have been created specifically for Tufts Medicare Preferred).
- May 11, 2010: No changes
- May 10, 2011: No changes
- February 14, 2012: No changes
- 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.
- July 9, 2013: No changes.
- September 10, 2013: Clarified criteria 3a to include Chronic Dry Eye Syndrome, Keratitis Sicca, and Xerophthalmia.
- September 9, 2014: No changes.
- September 16, 2015: No changes.
- January 1, 2016: Administrative change to rebranded template applicable to Tufts Health Direct.
- June 14, 2016: No changes. Effective June 20, 2016, Medical Necessity Guideline applies to Tufts Health Together.
- 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).
- April 11, 2017: Administrative update, Adding Tufts Health RITogether to the template.
- November 14, 2017: Criteria for Together were removed from this MNG. Minor wording edits to overview section and Restasis criteria.
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. They are used in conjunction with a Member’s benefit document and in coordination with the Member’s physician(s). 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.

This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan Members or to certain delegated service arrangements. Unless otherwise noted in the Member’s benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLink℠ Members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence.

For Tufts Health Plan Medicare Preferred, please refer to Tufts Health Plan Medicare Preferred Prior Authorization Criteria.

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.