TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: Sublingual Allergy Immunotherapy

Effective: January 1, 2016

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

This Pharmacy Medical Necessity Guidelines applies to the following:	Fax Numbers:
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 Freedom Plan products** ☐ Tufts Health Freedom Plan - large group plans ☐ Tufts Health Freedom Plan - small group plans	RXUM: 617.673.0988

OVERVIEW

FDA-APPROVED INDICATIONS

The FDA has approved three sublingual immunotherapy (SLIT) medications: Oralair, Grastek, and Ragwitek. All three agents received FDA approval as immunotherapy for the treatment of pollen-induced allergic rhinitis (hay fever), with or without conjunctivitis (eye inflammation).

Each allergen extract provides treatment for specific pollen types:

- Oralair – five grass pollens (sweet vernal, orchard, perennial rye, Timothy, and Kentucky grass)
- Grastek – Timothy grass pollen
- Ragwitek – short ragweed pollen

Oralair and Grastek are approved for children and adults. Oralair is approved for 10 to 65 years of age and Grastek for 5 to 65 years of age. Ragwitek is approved only in adults 18 through 65 years of age.

SLIT medications contain small amounts of an allergen extract. Exposure to the allergen allows the immune system to become less sensitive to the allergen. The natural response to the allergen is decreased, resulting in reduction in allergy symptoms.

COVERAGE GUIDELINES

The plan may authorize coverage of sublingual immunotherapy medications (SLIT) for Members when **all** of the following criteria for a particular regimen are met and limitations do not apply:

Oralair

1. Documentation the Member is between the ages 10 and 65 years old.

AND

2. Confirmation of a positive skin test or in vitro testing for pollen-specific IgE antibodies for any of the following allergens: sweet vernal, orchard, perennial rye, Timothy, or Kentucky grass within the past 2 years.

AND

3. The medication is prescribed by, or is based on the recommendations and consult of, an allergist or immunologist.

AND

4. The Member has tried and failed or had an insufficient response or intolerance to at least two of the following: oral antihistamines, nasal antihistamines, or nasal corticosteroids.

Grastek

1. Documentation the Member is between the ages 5 and 65 years old

AND

2. Confirmation of a positive skin test or in vitro testing for pollen-specific IgE antibodies for the following allergen: Timothy grass pollen within the past 2 years

AND

3. The medication is prescribed by, or is based on the recommendations and consult of, an allergist or immunologist

AND

4. The Member has tried and failed or had an insufficient response or intolerance to at least two of the following: oral antihistamines, nasal antihistamines, or nasal corticosteroids

Ragwitek

1. Documentation the Member is between the ages 18 and 65 years old

AND

2. Confirmation of a positive skin test or in vitro testing for pollen-specific IgE antibodies for the following allergen: short ragweed pollen within the past 2 years

AND

3. The medication is prescribed by, or is based on the recommendations and consult of, an allergist or immunologist

AND

4. The Member has tried and failed or had an insufficient response or intolerance to at least two of the following: oral antihistamines, nasal antihistamines, or nasal corticosteroids

LIMITATIONS

1. Coverage will be limited to 30 sublingual tablets per 30 days.
2. The length of approval will be for 2 years; subsequent approval will require a new authorization.

CODES

None

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APPROVAL HISTORY

July 8, 2014: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- July 14, 2015: No Changes
- January 1, 2016: Administrative change to rebranded template.

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^{SM} 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.