Pharmacy Medical Necessity Guidelines:  
Sublingual Allergy Immunotherapy  

Effective: October 1, 2018

<table>
<thead>
<tr>
<th>Prior Authorization Required</th>
<th>✓</th>
<th>Type of Review – Care Management</th>
<th>✓</th>
<th>Type of Review – Clinical Review</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Covered</td>
<td></td>
<td>Pharmacy (RX) or Medical (MED) Benefit</td>
<td>RX</td>
<td>Department to Review</td>
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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**
Sublingual immunotherapy 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.

**FDA-APPROVED INDICATIONS**
Grastek, Oralair, and Ragwitek are indicated as immunotherapy for the treatment of pollen-induced allergic rhinitis (hay fever), with or without conjunctivitis (eye inflammation) confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for the following:

- Oralair: sweet vernal, orchard, perennial rye, Timothy, and Kentucky blue grass mixed pollens
- 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.

Odactra (house dust mite allergen extract) is indicated for immunotherapy for house dust mite induced allergic rhinitis, with or without conjunctivitis, confirmed by in vitro testing for IgE antibodies to Dermatophagoides farina or Dermatophagoides pteronyssinus house dust mites, or skin testing to licensed house dust mite allergen extracts. Odactra is approved for use in adults 18 through 65 years of age.

**COVERAGE GUIDELINES**
The plan may authorize coverage of a sublingual immunotherapy medications medication for Members when all of the following criteria are met:

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

AND
4. Documentation the Member has tried and failed or had an insufficient response or intolerance to at least two generic oral antihistamines, nasal antihistamines, or nasal corticosteroids

**Odactra**
1. Documentation the Member is between the ages 18 and 65 years old
2. Confirmation of one of the following:
   - In vitro testing for IgE antibodies to Dermatophagoides farina or Dermatophagoides pteronyssinus house dust mites
   - Skin testing to licensed house dust mite allergen extracts
3. Documentation the medication is prescribed by, or is based on the recommendations and consult of, an allergist or immunologist
4. Documentation the Member has tried and failed or had an insufficient response or intolerance to at least two generic oral antihistamines, nasal antihistamines, or nasal corticosteroids

**Oralair**
1. Documentation the Member is between the ages 10 and 65 years old
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
3. Documentation the medication is prescribed by, or is based on the recommendations and consult of, an allergist or immunologist
4. Documentation the Member has tried and failed or had an insufficient response or intolerance to at least two generic oral antihistamines, nasal antihistamines, or nasal corticosteroids

**Ragwitek**
1. Documentation the Member is between the ages 18 and 65 years old
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
3. Documentation the medication is prescribed by, or is based on the recommendations and consult of, an allergist or immunologist
4. Documentation the Member has tried and failed or had an insufficient response or intolerance to at least two generic oral antihistamines, nasal antihistamines, or nasal corticosteroids

**LIMITATIONS**
1. The length of approval will be for 2 years subsequent approval will require a new authorization.
2. The following quantity limitations apply:

<table>
<thead>
<tr>
<th>Medication</th>
<th>Limitation</th>
</tr>
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<tbody>
<tr>
<td>Grastek</td>
<td>30 sublingual tablets per 30 days</td>
</tr>
<tr>
<td>Odactra</td>
<td>30 sublingual tablets per 30 days</td>
</tr>
<tr>
<td>Oralair</td>
<td>30 sublingual tablets per 30 days</td>
</tr>
<tr>
<td>Ragwitek</td>
<td>30 sublingual tablets per 30 days</td>
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**CODES**
None

**REFERENCES**

**APPROVAL HISTORY**
July 8, 2015: 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 applicable to Tufts Health Direct.
- July 12, 2016: No changes. Effective July 12, 2016 Medical Necessity Guideline applies to Tufts Health Together.
- July 11, 2017: No changes.
- April 10, 2018: Added criteria for Odactra. Effective 10/1/18, criteria for Oralair, Grastek, and Ragwitek were updated to require trial and failure of two generic oral antihistamines, nasal antihistamines, or nasal corticosteroids.
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 CareLinkSM 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.

Provider Services