Pharmacy Policy Bulletin

**Title:** Sublingual Immunotherapy

**Policy #:** Rx.01.158

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, gender or quantity restrictions. Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

**Intent:**

Grass pollen allergen extract-5 grass (Oralair®), grass pollen allergen extract-timothy grass (Grastek®), and short ragweed pollen allergen extract (Ragwitek®) are indicated as immunotherapy for the treatment of grass pollen-induced allergic rhinitis with or without conjunctivitis. It is not indicated for the immediate relief of allergy symptoms.

The use of grass pollen allergen extract-5 grass (Oralair®), grass pollen allergen extract-timothy grass (Grastek®), and short ragweed pollen allergen extract (Ragwitek®) requires prior authorization (i.e. clinical pharmacist and/or Medical Director review).

**Description:**

Grass pollen allergen extract-5 grass (Oralair®) contains extract from Timothy grass; Ragwitek® contains extract from short ragweed; and Oralair® contains a mix of the following five pollens: Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Bluegrass. While the exact mechanisms have not been fully elucidated, specific immunotherapy may act by inducing a switch from T helper 2 cell response to T helper 1 response resulting in decreased interleukin-4 (IL-4) and IL-5 and increased IL-10, production of IgG-blocking antibodies that compete with IgE antibodies for allergen binding, proliferation of regulatory T lymphocytes and cytokines, and decreases in mast cells, eosinophils, and early- and late-phase allergic responses.

**Policy:**

**INITIAL CRITERIA**

ORALAIR® is approved when ALL of the following inclusion criteria are met:

1. Member is 10 through 65 years of age
2. Diagnosis of grass pollen-induced allergic rhinitis with or without conjunctivitis
3. Positive skin test or in vitro testing for pollen-specific IgE antibodies for any of the five grass species contained in Oralair
4. Prescribed by the prescriber that conducted the above allergy testing

**REAUTHORIZATION CRITERIA**
Oralair® is re-approved when BOTH of the following inclusion criteria are met:
1. Member under 65 years of age
2. Annually reviewed and prescribed by an appropriate provider experienced in immunotherapy
Authorizations for Oralair® will be granted for a period of 1 year.

**INITIAL CRITERIA**
GRASTEK® is approved when ALL of the following inclusion criteria are met:
1. Member is 5 through 65 years of age
2. Diagnosis of grass pollen-induced allergic rhinitis with or without conjunctivitis
3. Positive skin test or in vitro testing for pollen-specific IgE antibodies for Timothy grass or cross-reactive grass pollens
4. Prescribed by the prescriber that conducted the above allergy testing

**REAUTHORIZATION CRITERIA**
Grastek® is re-approved when BOTH of the following inclusion criteria are met:
1. Member under 65 years of age
2. Annually reviewed and prescribed by an appropriate provider experienced in immunotherapy
Authorizations for Grastek® will be granted for a period of 1 year.

**INITIAL CRITERIA**
Ragwitek® is approved when ALL of the following inclusion criteria are met:
1. Member is 18 through 65 years of age
2. Diagnosis of ragweed pollen-induced allergic rhinitis with or without conjunctivitis
3. Positive skin test or in vitro testing for pollen-specific IgE antibodies for short ragweed pollen
4. Prescribed by the prescriber that conducted the above allergy testing

**REAUTHORIZATION CRITERIA**
Ragwitek® is re-approved when BOTH of the following inclusion criteria are met:
1. Member under 65 years of age
2. Annually reviewed and prescribed by an appropriate provider experienced in immunotherapy
Authorizations for Ragwitek® will be granted for a period of 1 year.

**Black Box Warning:**
**Severe allergic reactions:** Grass pollen allergen extract can cause life-threatening allergic reactions such as anaphylaxis and severe laryngopharyngeal restriction. Do not administer to patients with severe, unstable, or uncontrolled asthma. Observe patients in the office for at least 30 minutes following the initial dose. Prescribe auto-injectable epinephrine, instruct and train patients on its appropriate use, and instruct patients to seek immediate medical care upon its use. Grass pollen allergen extract may not be suitable for patients with certain underlying medical conditions that may reduce their ability to survive a serious allergic reaction. Grass pollen allergen extract may not be suitable for patients who may be unresponsive to epinephrine or inhaled bronchodilators, such as those taking beta-blockers.

**Guidelines:**
Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

**BENEFIT APPLICATION**
Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the pharmacy benefits of the Company’s products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

**References:**


RAGWITEK prescribing information. Merck & Co. Whitehouse Station, NJ. April 2014.


**Applicable Drugs:**

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
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<tr>
<td>Grastek</td>
<td>grass pollen allergen extract-timothy grass</td>
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<tr>
<td>Oralair</td>
<td>grass pollen allergen extract-5 grass</td>
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<tr>
<td>Ragwitek</td>
<td>short ragweed pollen allergen extract</td>
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**Cross References:**
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<th>Policy Version Number:</th>
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<tr>
<td>P&amp;T Approval Date:</td>
<td>July 10, 2014</td>
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<td>Policy Effective Date:</td>
<td>February 01, 2015</td>
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