Allergen-Specific Immunotherapy
Pharmacy Coverage Policy

P&T Review Date: 06/24/2015
UMC Revision Date: 05/21/2015
Reviewer Initials: LH
Effective Date: 07/15/2015

Policy type: PA with QL
Program type: Standard
Specialty: Yes
Line of Business: Commercial, Med D 2014

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
<th>GPI</th>
<th>Drug Class</th>
</tr>
</thead>
<tbody>
<tr>
<td>GRASTEK</td>
<td>Timothy Grass Pollen Allergen Extract</td>
<td>201000480007**</td>
<td>Allergen-Specific Immunotherapy</td>
</tr>
<tr>
<td>ORALAIR</td>
<td>Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass Mixed Pollens Allergen Extract</td>
<td>201099052007**</td>
<td>Allergen-Specific Immunotherapy</td>
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<tr>
<td>RAGWITEK</td>
<td>Short Ragweed Pollen Allergen Extract</td>
<td>201000602007**</td>
<td>Allergen-Specific Immunotherapy</td>
</tr>
</tbody>
</table>

CRITERIA FOR COVERAGE/NONCOVERAGE

GRASTEK® (Timothy Grass Pollen Allergen Extract), ORALAIR® (Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass Mixed Pollens Allergen Extract) and RAGWITEK® (Short Ragweed Pollen Allergen Extract) will be considered for coverage under the pharmacy benefit program when the following criteria are met:

- Patient has one of the following product specific requirements:
  - Diagnosis of grass pollen-induced allergic rhinitis and treatment will be initiated 3 months before the expected onset of the grass pollen season (GRASTEK only)
  - Diagnosis of grass pollen-induced allergic rhinitis and treatment will be initiated 4 months before the expected onset of the grass pollen season (ORALAIR only)
  - Diagnosis of short ragweed pollen-induced allergic rhinitis and treatment will be initiated 3 months before the expected onset of the ragweed pollen season (RAGWITEK only)

AND

- Patient has a positive skin test or in vitro test for one of the listed pollen-specific IgE antibodies:
  - Timothy Grass or cross-reactive grass pollens (GRASTEK only)
  - Any of the five grass species including sweet vernal, orchard, perennial rye, timothy or Kentucky blue grass mixed pollens (ORALAIR only)
  - Short ragweed pollen (RAGWITEK only)

AND

- Patient’s age is within the appropriate FDA approved range for the prescribed product:
  - 5 to 65 years of age (GRASTEK only)
  - 10 to 65 years of age (ORALAIR only)
  - 18 to 65 years of age (RAGWITEK only)

AND
- Patient does not have any of the following contraindications or exclusions to therapy:
  o Severe, unstable or uncontrolled asthma
  o History of any severe systemic allergic reaction or any severe local reaction to sublingual allergen immunotherapy
  o History of eosinophilic esophagitis
  o Hypersensitivity to any of the inactive ingredients contained in the product
  o Current oral inflammation or wound from previous pollen specific sublingual immunotherapy

AND
- Drug is prescribed by or in consultation with an allergist or immunologist

AND
- Patient will be monitored after the initial dose for at least 30 minutes in a healthcare facility under the supervision of a physician

AND
- Patient will be provided and educated on the proper use of an auto-injectable epinephrine product

AND
- Patient has tried and had an inadequate response, intolerance or contraindication to an intranasal corticosteroid and an antihistamine

Quantity Limit:
- GRASTEK and RAGWITEK will be subject to a quantity limit of 1 tablet per day
- ORALAIR 100 IR tablets will be subject to a quantity limit of 3 tablets per month
- ORALAIR 300 IR tablets will be subject to a quantity limit of 1 tablet per day

Reauthorization Criteria and Duration:
Authorization for continued use shall be reviewed at least every 12 months to ensure the patient has not developed any contraindications and has had an objective response to therapy demonstrated by one of the following:
- Patient has experienced improvement in the symptoms of their allergic rhinitis OR
- Patient has experienced a decrease in the number of medications needed to control allergy symptoms

GRASTEK (Timothy Grass Pollen Allergen Extract), ORALAIR (Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass Mixed Pollens Allergen Extract) and RAGWITEK (Short Ragweed Pollen Allergen Extract) are considered experimental/investigational for conditions not listed in this coverage policy section.