Allergen Extract Criteria

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Trade Name</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Timothy Grass Pollen Allergen Extract</td>
<td>Grastek®</td>
<td>Grass pollen induced allergic rhinitis with or without conjunctivitis</td>
</tr>
<tr>
<td>Short Ragweed Pollen Allergen Extract</td>
<td>Ragwitek™</td>
<td>Short ragweed pollen induced allergic rhinitis with or without conjunctivitis</td>
</tr>
<tr>
<td>Grass Pollen Extract</td>
<td>Oralair®</td>
<td>Moderate to severe seasonal grass (Kentucky Blue Grass, Orchard, Perennial Rye, Sweet Vernal and Timothy) pollen induced allergic rhinitis with or without conjunctivitis</td>
</tr>
</tbody>
</table>

**APPROVAL CRITERIA**

Approve pollen allergy extract for the following:

- Confirmed allergen by positive skin test or in vitro testing for pollen specific IgE antibodies for approved indication; **AND**
- Treatment is requested 12 weeks prior to season of allergen being treated (Grastek or Ragwitek) or 4 months prior to season of allergen being treated (Oralair only)

**DENIAL CRITERIA**

Deny pollen allergy extract for the following:

- Patient is less than 5 years of age (for Grastek only)
- Patient is less than 10 years of age (for Oralair only)
- Patient is less than 18 years of age (for Ragwitek only)
- Patient experienced a severe reaction post initial dose that was administered in the physician’s office
- Request is during active season of allergen (ragweed season - late summer – until fall (August – November; grass season – summer (June))
- Concomitant allergen immunotherapy
- History of severe, unstable or uncontrolled asthma
- History of eosinophilic esophagitis
LENGTH OF AUTHORIZATION

1 year
9 months (Oralair patients 10-17 years of age)

QUANTITY LIMIT

Quantity limit of 1 tablet per day for a total life time approval of 3 consecutive years (Grastek and Ragwitek)

Oralair 100 IR & 300 IR dose pack (1 dose pack per lifetime), 300 IR 1 tablet per day for a total life time approval of 1 year (patients age 5-17) or 3 consecutive years (patients over 18 years of age)

RENEWAL

- Treatment is requested 12 weeks prior to season of allergen being treated (Grastek or Ragwitek) or 4 months prior to season of allergen being treated (Oralair only)
- No renewal for Oralair for patients 10 – 17 years of age beyond 9 months approval

REFERENCES


<table>
<thead>
<tr>
<th>Review:</th>
<th>Reason for Review:</th>
<th>Date Approved:</th>
</tr>
</thead>
<tbody>
<tr>
<td>DUR Board</td>
<td>New</td>
<td>5/12/2015</td>
</tr>
<tr>
<td>Commissioner Approval</td>
<td></td>
<td>6/30/2015</td>
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