Overview
Grastek™, Odactra™, Oralair™, and Ragwitek™ are allergen-specific immunotherapies used to allow the immune system to become less sensitive to specific allergens and thereby, decrease allergy symptoms.

Coverage Guidelines

General Approval Criteria – for ALL drugs
Authorization may be granted for members who meet ALL the following criteria PLUS the respective Drug-Specific Criteria, and documentation has been submitted:
1. The prescriber is an allergist or immunologist, or the therapy has been recommended by a specialist via consult within the previous year.
2. Member does not have a diagnosis of severe or uncontrolled asthma.
3. Member has had a documented side effect, allergy, inadequate response, or treatment failure with at least one non-sedating antihistamine (e.g., loratadine, cetirizine, fexofenadine, etc.).
4. Member has had a documented side effect, allergy, inadequate response, or treatment failure with an intranasal corticosteroid.
5. Member has had a documented side effect, allergy, inadequate response, or treatment failure with an intranasal antihistamine.
6. Member has had a documented side effect, allergy, inadequate response, or treatment failure with a leukotriene modifier (e.g., montelukast, zafirlukast, etc.).
7. Member will be prescribed and trained to self-administer epinephrine rescue therapy.

Drug-Specific Criteria – for Grastek
Authorization may be granted for members who are new to AllWays Health Partners and has been stabilized on Grastek for an approvable indication by a specialist (allergist or immunologist) or under recommendation of a specialist via consult within the previous year.

OR
Authorization may be granted for members with a diagnosis of allergic rhinitis with or without conjunctivitis when ALL the following criteria are met:
1. Member is between the ages of 5 and 65.
2. Member has had a skin test or in vitro testing confirming pollen-specific immunoglobulin E (IgE) antibodies for Timothy grass or cross-reactive grass pollen.
3. Therapy will begin 12 weeks prior to the allergy season and will not exceed 3 consecutive years (including intervals between grass pollen seasons).

**Drug-Specific Criteria – for Odactra**
Authorization may be granted for members who are new to AllWays Health Partners and has been stabilized on Odactra for an approvable indication by a specialist (allergist or immunologist) or under recommendation of a specialist via consult within the previous year.

OR
Authorization may be granted for members with a diagnosis of house dust mite-induced (HDM) allergic rhinitis with or without conjunctivitis when ALL the following criteria are met:
1. Member is between the ages of 18 and 65.
2. Member has had a skin test or in vitro testing confirming pollen-specific immunoglobulin E (IgE) antibodies to Dermatophagoides farinae or D. pteronyssinus dust mites or skin testing to licensed HDM allergen extracts in adults 65 years of and younger.

**Drug-Specific Criteria – for Oralair**
Authorization may be granted for members who are new to AllWays Health Partners and has been stabilized on Oralair for an approvable indication by a specialist (allergist or immunologist) or under recommendation of a specialist via consult within the previous year.

OR
Authorization may be granted for members with a diagnosis of grass pollen-induced allergic rhinitis with or without conjunctivitis when ALL the following criteria are met:
1. Member is between the ages of 5 and 65.
2. Member has had a skin test or in vitro testing confirming pollen-specific immunoglobulin E (IgE) antibodies for any of the 5- grass species contained in this product (Sweet Vernal, Orchard, Perennial Rye, Timothy and Kentucky Blue Grass).
3. Therapy must begin 4 months prior to the expected onset of each specific grass pollen season. Safety of initiating treatment during grass pollen season or restarting treatment after missing a dose have not been established.

**Drug-Specific Criteria – for Ragwitek**
Authorization may be granted for members who are new to AllWays Health Partners and has been stabilized on Ragwitek for an approvable indication by a specialist (allergist or immunologist) or under recommendation of a specialist via consult within the previous year.

OR
Authorization may be granted for members with a diagnosis of short ragweed pollen-induced allergic rhinitis with or without conjunctivitis when ALL the following criteria are met:
1. Member is between the ages of 18 and 65.
2. Member has had a skin test or invtiro testing for pollen-specific IgE antibodies for short ragweed pollen.
3. Therapy will begin 12 weeks prior to the expected onset of each ragweed pollen season.

Limitations
1. Initial approvals will be for 12 months.
2. The following quantity limits apply:

<table>
<thead>
<tr>
<th>Medication Name</th>
<th>Quantity Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grastek</td>
<td>30 tablets per 30 days</td>
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<tr>
<td>Odactra</td>
<td>30 tablets per 30 days</td>
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<tr>
<td>Oralair</td>
<td>30 tablets per 30 days</td>
</tr>
<tr>
<td>Ragwitek</td>
<td>30 tablets per 30 days</td>
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</tbody>
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References
1. Oralair (Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Bluegrass mixed pollens allergen extract) [prescribing information]. Lenoir, NC: Greer Laboratories Inc; received November 2018.
2. Grastek (timothy grass pollen allergen extract) [prescribing information]. Whitehouse Station, NJ: Merck & Co, Inc; October 2017.
3. Odactra (house dust mite allergen extract) [prescribing information]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp; April 2017.
Review History
06/06/15 – Effective
04/25/16 – Reviewed
09/18/17 – Reviewed
02/26/18 – Reviewed in P&T Meeting
02/20/19 – Updated (Combined GRASTEK/ODACTRA/ORALAIR/RAGWITEK)

Disclaimer
AllWays Health Partners complies with applicable federal civil rights laws and does not discriminate or exclude people on the basis of race, color, national origin, age, disability, or sex.