

**Allergy-Specific Immunology:**  
**Grastek**  
**Odactra**  
**Oralair**  
**Ragwitek**  
**Effective 08/01/2025**

|                              |   |                         |  |  |
|------------------------------|---|-------------------------|--|--|
| <b>Plan</b>                  | <input type="checkbox"/> MassHealth UPPL<br><input checked="" type="checkbox"/> Commercial/Exchange |                         | <b>Program Type</b>                        | <input checked="" type="checkbox"/> Prior Authorization<br><input checked="" type="checkbox"/> Quantity Limit<br><input type="checkbox"/> Step Therapy |
| <b>Benefit</b>               | <input checked="" type="checkbox"/> Pharmacy Benefit<br><input type="checkbox"/> Medical Benefit    |                         |  |  |
| <b>Specialty Limitations</b> | N/A   |                         |  |  |
| <b>Contact Information</b>   | <b>Medical Benefit</b>  | <b>Pharmacy Benefit</b> | Phone: 833-895-2611<br>Phone: 800-711-4555 | Fax: 888-656-6671<br>Fax: 844-403-1029   |
| <b>Exceptions</b>            | N/A   |                         |  |  |

### 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.

- Grastek (Timothy grass pollen allergen extract) is an allergen extract indicated as immunotherapy for the treatment of grass pollen-induced allergic rhinitis with or without conjunctivitis confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for Timothy grass or cross-reactive grass pollens. It is approved for patients 5 through 65 years of age.
- Odactra (Dermatophagoides farinae and Dermatophagoides pteronyssinus) is an allergen extract indicated as immunotherapy for the treatment of house dust mite (HDM)-induced allergic rhinitis, with or without conjunctivitis, confirmed by positive in vitro testing for IgE antibodies to Dermatophagoides farina or Dermatophagoides pteronyssinus house dust mites or by positive skin testing to licensed house dust mite allergen extracts. It is approved for patients 5 through 65 years of age.
- Oralair (sweet vernal, orchard, perennial rye, timothy, and Kentucky blue grass mixed pollens allergens extract) is an allergen extract indicated as immunotherapy for the treatment of grass pollen-induced allergic rhinitis with or without conjunctivitis confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for any of the five grass species contained in Oralair. It is approved for patients 5 through 65 years of age.
- Ragwitek (short ragweed pollen) is an allergen extract indicated as immunotherapy for the treatment of short ragweed pollen-induced allergic rhinitis, with or without conjunctivitis, confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for short ragweed pollen. It is approved for patients 5 through 65 years of age.

### Coverage Guidelines

Authorization may be reviewed for members new to the plan within the past 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs

**OR**

Authorization may be granted for members when all of the following criteria are met:

**General Approval Criteria – for ALL drugs**

Authorization may be granted for members who meet ALL the following criteria **PLUS** the respective drug-specific criteria (below):

1. Prescriber is an allergist or immunologist, or the therapy has been recommended by a specialist via consult within the previous year.
2. Documentation 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. Documentation member will be prescribed and trained to self-administer epinephrine rescue therapy
8. Drug-specific criteria are met

**Drug-Specific Criteria – Grastek (Timothy grass pollen allergen extract)**

1. Diagnosis of grass pollen-induced allergic rhinitis with or without conjunctivitis
2. Member is 5 to 65 years of age
3. 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.
4. 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 – Odactra (Dermatophagoides farinae and Dermatophagoides pteronyssinus)**

1. Diagnosis of house dust mite induced (HDM) allergic rhinitis with or without conjunctivitis
2. Member is 5 to 65 years of age
3. 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 – Oralair (sweet vernal, orchard, perennial rye, timothy, and Kentucky blue grass mixed pollens)**

1. Diagnosis of grass pollen-induced allergic rhinitis with or without conjunctivitis
2. Member is 5 to 65 years of age
3. 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).
4. Therapy with Oralair will begin 4 months prior to the expected onset of each specific grass pollen season

**Drug-Specific Criteria – Ragwitek (short ragweed pollen)**

1. Diagnosis of short ragweed pollen-induced allergic rhinitis with or without conjunctivitis



2. Member is 5 to 65 years of age
3. Member has had a skin test or invitro testing for pollen specific IgE antibodies for short ragweed pollen.
4. Therapy with Ragwitek will begin 12 weeks prior to the expected onset of each ragweed pollen season.

#### Limitations

1. Approvals will be granted for 12 months.
2. The following quantity limits apply:

| Medication Name | Quantity Limit         |
|-----------------|------------------------|
| Grastek         | 30 tablets per 30 days |
| Odactra         | 30 tablets per 30 days |
| Oralair         | 30 tablets per 30 days |
| Ragwitek        | 30 tablets per 30 days |

#### References

1. Creticos PS, Esch RE, Couroux P, et al. Randomized, double-blind, placebo-controlled trial of standardized ragweed sublingual-liquid immunotherapy for allergic rhinoconjunctivitis. J Allergy Clin Immunol 2014; 133:751.
2. Di Bona D, Plaia A, Leto-Barone MS, et al. Efficacy of subcutaneous and sublingual immunotherapy with grass allergens for seasonal allergic rhinitis: a meta-analysis-based comparison. J Allergy Clin Immunol 2012; 130:1097.
3. Grastek (Timothy grass pollen allergen extract) [prescribing information]. Swindon, Wiltshire, UK: Catalent Pharma Solutions Limited; December 2019.
4. Hankin CS, Cox L, Bronstone A, Wang Z. Allergy immunotherapy: reduced health care costs in adults and children with allergic rhinitis. J Allergy Clin Immunol 2013; 131:1084.
5. Odactra (house dust mite allergen extract) [prescribing information]. Swindon, Wiltshire, UK: Catalent Pharma Solutions Limited; February 2025.
6. Oralair (Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Bluegrass mixed pollens allergen extract) [prescribing information]. Lenoir, NC: Greer Laboratories Inc; November 2018.
7. Pajno GB, Caminiti L, Crisafulli G, et al. Direct comparison between continuous and coseasonal regimen for sublingual immunotherapy in children with grass allergy: a randomized controlled study. Pediatr Allergy Immunol 2011; 22:803.
8. Ragwitek (short ragweed pollen allergen extract) [prescribing information]. Swindon, Wiltshire, UK: Catalent Pharma Solutions Limited; April 2021.
9. Scadding GW, Calderon MA, Shamji MH, et al. Effect of 2 Years of Treatment With Sublingual Grass Pollen Immunotherapy on Nasal Response to Allergen Challenge at 3 Years Among Patients With Moderate to Severe Seasonal Allergic Rhinitis: The GRASS Randomized Clinical Trial. JAMA 2017; 317:615.
10. Tabar AI, Arroabarren E, Echechipía S, et al. Three years of specific immunotherapy may be sufficient in house dust mite respiratory allergy. J Allergy Clin Immunol 2011; 127:57.
11. Van Dyken AM, Smith PK, Fox TL. Clinical case of anaphylaxis with sublingual immunotherapy: house dust mite allergen. J Allergy Clin Immunol Pract 2014; 2:485.

#### 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)

01/20/2021 – Reviewed Jan P&T.

05/14/2025 – Reviewed and updated at May P&T. Added language for members who are new to the plan.

Specified diagnosis for each agent. Updated minimum ages for Odactra and Ragwitek from 18 years of age to 5 years of age to align with updated FDA-approved package labeling. Effective 08/01/2025.

