



**Allergy-Specific Immunology**  
**GRASTEK™/ODACTRA™/ORALAIR™/RAGWITEK™**  
**Effective 02/20/2019**

<b>Plan</b>	<input checked="" type="checkbox"/> MassHealth <input checked="" type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization
<b>Benefit</b>	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit (NLX)		<input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Specialty Limitations</b>	N/A		
<b>Contact Information</b>	<b>Specialty Medications</b>		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	<b>Non-Specialty Medications</b>		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	<b>Medical Specialty Medications (NLX)</b>		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
<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.

**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 Odaetra**

Authorization may be granted for members who are new to AllWays Health Partners and has been stabilized on Odaetra 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 invitro 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:

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. 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
4. Ragwitek (short ragweed pollen allergen extract) [prescribing information]. Whitehouse Station, NJ: Merck Sharp & Dohme; March 2017.
5. 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.
6. 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.
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. 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.
9. 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.
10. 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.
11. 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.
12. Food and Drug Administration. Grastek FDA Advisory Committee briefing document. Dec. 2013. URL: [www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtheBiologics/AllergenicProductsAdvisoryCommittee/UCM378092.pdf](http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtheBiologics/AllergenicProductsAdvisoryCommittee/UCM378092.pdf). Available from Internet.



**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**

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