Mass General Brigham
Health Plan

Allergy-Specific Immunology
GRASTEK™/ODACTRA™/ORALAIR™/RAGWITEK™
Effective 01/20/2021

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit (NLX)		
Specialty Limitations	N/A		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	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
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	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 the plan 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 the plan 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 the plan 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 the plan 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; August 2020.
3. Odactra (house dust mite allergen extract) [prescribing information]. Swindon, Wiltshire, UK: Catalent Pharma Solutions Limited; August 2019
4. Ragwitek (short ragweed pollen allergen extract) [prescribing information]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp; August 2020
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/BloodVaccinesandOthe biologics/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)
01/20/2021 – Reviewed Jan P&T.