

Pharmacy Policy Bulletin

Title: Allergen Specific Immunotherapy (SL)

Policy #: Rx.01.158

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

▶ **Intent:**

The intent of this policy is to communicate the medical necessity criteria for house dust mite allergen extract (Odactra™), grass pollen allergen extract-5 grass (Oralair®), grass pollen allergen extract-timothy grass (Grastek®), and short ragweed pollen allergen extract (Ragwitek®) as provided under the member's prescription drug benefit.

▶ **Description:**

Allergic rhinitis is a persistent condition that typically requires ongoing therapy. Allergen avoidance along with pharmacologic therapy with nasal corticosteroids and oral antihistamines are standard management. Allergen immunotherapy is reserved for severe or refractory cases. Sublingual immunotherapy involves the application of the allergen to the sublingual tissue. In the case of Odactra™, Oralair®, Grastek®, and Ragwitek®, the allergen is in a sublingual tablet which is self-administered, after the first dose.

The exact mechanism of sublingual allergen immunotherapy has not been fully elucidated. Allergen extracts given sublingually are primarily taken up by dendritic cells in the mucosa and presented to T cells in the draining lymph nodes. Likely mechanisms of action include activation of T regulatory cells and downregulation of mucosal mast cells. Within the oral and sublingual mucosa, effector cells, such as mast cells, are less numerous, which may account for the lower rates of adverse systemic allergic reactions seen with sublingual immunotherapy.

Timothy grass pollen allergen extract (Grastek®) is 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 in persons 5 through 65 years of age.

Short ragweed pollen allergen extract (Ragwitek®) is 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 in adults 18 through 65 years of age.

Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass mixed pollens allergen extract (Oralair®) is 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 this product in persons 10 through 65 years of age.

Dermatophagoides farinae or Dermatophagoides pteronyssinus house dust mite allergen extract (Odactra™) is indicated as immunotherapy for house dust mite (HDM)-induced allergic rhinitis, with or without conjunctivitis, confirmed by in vitro testing for IgE antibodies to Dermatophagoides farinae or Dermatophagoides pteronyssinus house dust mites, or skin testing to licensed house dust mite allergen extracts. Odactra™ is approved for use in adults 18 through 65 years of age.

▸ **Policy:**

INITIAL CRITERIA

Odactra™, Oralair®, Grastek® or Ragwitek® is approved when ALL of the following are met:

1. FDA approved indication; and
2. Patient has a positive skin test or in vitro test for ONE of the listed pollen-specific IgE antibodies:
 - a. Timothy Grass or cross-reactive grass pollens (GRASTEK® only)
 - b. Any of the five grass species including sweet vernal, orchard, perennial rye, timothy or Kentucky blue grass mixed pollens (ORALAIR® only)
 - c. Short ragweed pollen (RAGWITEK® only)
 - d. Dermatophagoides farina or Dermatophagoides pteronyssinus house dust mites (ODACTRA™ only)
3. Prescribed by the prescriber that conducted the above allergy testing; and
4. Patient does not have any of the following:
 - a. Severe, unstable or uncontrolled asthma
 - b. History of eosinophilic esophagitis
5. Patient has had an inadequate response or inability to tolerate intranasal corticosteroid and an antihistamine

REAUTHORIZATION CRITERIA

Odactra™, Oralair®, Grastek® or Ragwitek® is re-approved when ALL of the following are met:

1. Use in the age group supported by FDA labeling; and

2. Annually reviewed and prescribed by an appropriate provider experienced in immunotherapy; and
3. Patient has experienced improvement in the symptoms of their allergic rhinitis OR a decrease in the number of medications needed to control allergy symptoms

Authorizations for Odactra™, Oralair®, Grastek® or Ragwitek™ will be granted for a period of 1 year.

▶ **Black Box Warning:**

Severe allergic reactions:

Odactra™, Grastek®, Oralair® and Ragwitek™ can cause life-threatening allergic reactions such as anaphylaxis and severe laryngopharyngeal restriction.

Do not administer Odactra™, Grastek®, Oralair® and Ragwitek™ to patients with severe, unstable or uncontrolled asthma. Observe patients in the office for at least 30 minutes following the initial dose.

Prescribe auto-injectable epinephrine, instruct and train patients on its appropriate use, and instruct patients to seek immediate medical care upon its use.

Odactra™, Grastek®, Oralair® and Ragwitek™ may not be suitable for patients with certain underlying medical conditions that may reduce their ability to survive a serious allergic reaction.

Odactra™, Grastek®, Oralair® and Ragwitek™ may not be suitable for patients who may be unresponsive to epinephrine or inhaled bronchodilators, such as those taking beta-blockers.

▶ **Guidelines:**

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

▶ **References:**

Creticos PS. Sublingual immunotherapy for allergic rhinoconjunctivitis and asthma. UpToDate. Available at: <http://www.uptodate.com/contents/sublingual-immunotherapy-for-allergic-rhinoconjunctivitis-and-asthma>. Accessed July 24, 2018.


De Shazo RD, Kemp SF. Pharmacotherapy of allergic rhinitis. UpToDate. Available at: https://www.uptodate.com/contents/pharmacotherapy-of-allergic-rhinitis?search=pharmacotherapy-of-allergic-rhinitis.&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1. Accessed July 24, 2018. Grastek® (Timothy grass pollen allergen extract) [package insert]. Whitehouse Station NJ. Merck and Co, Inc. June 2014. Accessed July 24, 2018.

Oralair® (Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass mixed pollens allergen extract) [package insert]. Lenoir NC. Greer Laboratories, Inc. October 2014. Accessed July 24, 2018.

Ragwitek® (short ragweed pollen allergen extract) [package insert]. Whitehouse Station NJ. Merck and Co, Inc. March 2016. Accessed July 24, 2018.

Odactra™ (and house dust mite allergen extract) [package insert]. Whitehouse Station NJ. Merck and Co, Inc. 2017. Accessed May 21, 2018. Available from:
<https://www.fda.gov/downloads/biologicsbloodvaccines/allergenics/ucm544382.pdf>

Applicable Drugs:

 Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand Name	Generic Name
Grastek®	grass pollen allergen extract-timothy grass
Oralair®	grass pollen allergen extract-5 grass
Ragwitek®	short ragweed pollen allergen extract
Odactra™	house dust mite allergen extract

Cross References:

N/A

Policy Version Number:	8.00
P&T Approval Date:	July 12, 2018
Policy Effective Date:	October 01, 2018
Next Required Review Date:	July 12, 2019

The Policy Bulletins on this web site were developed to assist the Company in administering the provisions of the respective benefit programs, and do not constitute a contract. If you have coverage through the Company, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. Company does not provide health care services, medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of the Company. If you have a specific medical condition, please consult with your doctor. The Company reserves the right at any time to change or update its Policy Bulletins.