

Pharmacy Policy Bulletin: J-0402 Sublingual Immunotherapies - Medicare	
Number: J-0402	Category: Prior Authorization
Line(s) of Business: <input type="checkbox"/> Commercial <input type="checkbox"/> Healthcare Reform <input checked="" type="checkbox"/> Medicare	Benefit(s): Not Applicable
Region(s): <input checked="" type="checkbox"/> All <input type="checkbox"/> Delaware <input type="checkbox"/> New York <input type="checkbox"/> Pennsylvania <input type="checkbox"/> West Virginia	Additional Restriction(s): None
Version: J-0402-020	Original Date: 08/19/2014
Effective Date: 06/24/2024	Review Date: 06/05/2024

Drugs Product(s):	<ul style="list-style-type: none"> • Oralair (Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass Mixed Pollens Allergens Extract) • Grastek (Timothy Grass Pollen Allergen Extract) • Ragwitek (Short Ragweed Pollen Allergen Extract) • Odactra (House Dust Mite Allergen Extract)
FDA-Approved Indication(s):	<ul style="list-style-type: none"> • Oralair: treatment of grass pollen-induced allergic rhinitis (with or without conjunctivitis) confirmed by positive skin test or <i>in vitro</i> testing for pollen-specific IgE antibodies for any of the five grass species contained in this product (Sweet Vernal, Orchard, Perennial Rye, Timothy, or Kentucky Blue Grass) in persons 5 through 65 years of age • Grastek: treatment of grass pollen-induced allergic rhinitis (with or without conjunctivitis) confirmed by positive skin test or <i>in vitro</i> testing for pollen-specific IgE antibodies for Timothy grass or cross-reactive grass pollens in persons 5 through 65 years of age • Ragwitek: treatment of short ragweed pollen-induced allergic rhinitis (with or without conjunctivitis) confirmed by positive skin test or <i>in vitro</i> testing for pollen-specific IgE antibodies for short ragweed pollen in persons 5 through 65 years of age • Odactra: treatment of house dust mite (HDM)-induced allergic rhinitis (with or without conjunctivitis) confirmed by <i>in vitro</i> testing for IgE antibodies to <i>Dermatophagoides farinae</i> or <i>Dermatophagoides pteronyssinus</i> house dust mites, or skin testing to licensed house dust mite allergen extracts in persons 12 through 65 years of age

Background:	<ul style="list-style-type: none"> • Oralair, Grastek, Ragwitek, and Odactra are considered immunotherapy. The precise mechanism of the allergen immunotherapy is unknown. • Allergic rhinitis is a common and chronic immunoglobulin E–mediated respiratory illness that can affect quality of life and productivity and exacerbate other conditions such as asthma. Treatment should be based on the patient's age and severity of symptoms. Patients should be educated about their condition and advised to avoid known allergens. • Intranasal corticosteroids are first-line therapy for persistent symptoms affecting quality of life. More severe disease that does not respond to intranasal corticosteroids should be treated with second-line therapies, including
--------------------	--

antihistamines, decongestants, cromolyn, leukotriene receptor antagonists, and nonpharmacologic therapies such as nasal irrigation.

- Subcutaneous or sublingual immunotherapy should be considered if usual treatments do not adequately control symptoms and in patients with allergic asthma.
- Allergen immunotherapy or subcutaneous immunotherapy (SCIT) (i.e., desensitization, hyposensitization, allergy injection therapy, or "allergy shots"), is the repeated administration of specific allergens to patients with immune globulin E (IgE)-mediated conditions. The aim is to modify or stop the allergy by reducing the strength of the IgE response.
- Prescribing Considerations:
 - The medication should be prescribed by an allergy specialist, otolaryngologist (ENT) physician, or immunologist.
 - Sublingual immunotherapies have a black box warning for severe allergic reactions. Members with certain underlying conditions who may not be able to survive a serious allergic reaction. Members who may be unresponsive to epinephrine or inhaled bronchodilators, such as those taking beta-blockers may not be suitable for these therapies.
 - Contraindications include severe, unstable or uncontrolled asthma, history of any severe systemic allergic reaction, history of any severe local reaction to sublingual allergen immunotherapy, and a history of eosinophilic esophagitis.
 - Auto-injectable epinephrine should be prescribed along with sublingual immunotherapy. Instruct and train patients on appropriate epinephrine use and instruct patients to seek immediate medical care upon its use.
 - The first dose should be administered in the physician's office and the patient should be observed for at least 30 minutes following the initial dose.
 - Sublingual immunotherapies are not indicated for immediate relief of allergy symptoms.
 - Ragwitek and Oralair do not have data available regarding the safety of starting treatment during the pollen season or restarting treatment after missing a dose.
 - Oralair treatment should not be initiated in-season but 4 months prior to allergy season, which is typically during the summer months, starting in May.
 - Ragwitek treatment should not be initiated in-season but 3 months prior to allergy season, which is typically during the fall months, starting in August.
 - Grastek treatment should not be initiated in-season but 3 months prior to allergy season, which is typically during the summer months, starting in May.

Approval Criteria

I. Initial Authorization

A. Oralair

When a benefit, coverage of Oralair may be approved when all of the following criteria are met (**1. through 5.**):

1. The member is between the ages of 5 and 65 years.
2. The member has a diagnosis of allergic rhinitis due to Sweet Vernal, Orchard, Perennial Rye, Timothy, or Kentucky Blue Grass pollen.

3. The member has allergic rhinitis with or without conjunctivitis confirmed by one (1) of the following **(a. or b.)**:
 - a. A pollen specific positive skin test
 - b. In vitro testing for pollen-specific IgE antibodies
4. The member has experienced therapeutic failure, contraindication, or intolerance to all of the following **(a. and b.)**:
 - a. An intranasal steroid
 - b. One (1) of the following **(i., ii., or iii.)**:
 - i. An oral non-sedating antihistamine
 - ii. An intranasal antihistamine
 - iii. An intranasal anticholinergic agent
5. The member has a concurrent prescription for an epinephrine auto-injector.

B. Grastek

When a benefit, coverage of Grastek may be approved when all of the following criteria are met **(1. through 5.)**:

1. The member is between the ages of 5 and 65 years.
2. The member has a diagnosis of allergic rhinitis due to Timothy grass pollen or cross-reactive grass pollens (e.g., Sweet Vernal, Orchard, Perennial Rye, Timothy, Kentucky Blue Grass pollen, Redtop, or meadow fescue).
3. The member has allergic rhinitis with or without conjunctivitis confirmed by one (1) of the following **(a. or b.)**:
 - a. A pollen specific positive skin test
 - b. In vitro testing for pollen-specific IgE antibodies
4. The member has experienced therapeutic failure, contraindication, or intolerance to all of the following **(a. and b.)**:
 - a. An intranasal steroid
 - b. One (1) of the following **(i., ii., or iii.)**:
 - i. An oral non-sedating antihistamine
 - ii. An intranasal antihistamine
 - iii. An intranasal anticholinergic agent
5. The member has a concurrent prescription for an epinephrine auto-injector.

C. Ragwitek

When a benefit, coverage of Ragwitek may be approved when all of the following criteria are met **(1. through 5.)**:

1. The member is between the ages of 5 and 65 years.
2. The member has a diagnosis of allergic rhinitis due to ragweed pollen.
3. The member has allergic rhinitis with or without conjunctivitis confirmed by one (1) of the following **(a. or b.)**:
 - a. A pollen specific positive skin test
 - b. In vitro testing for pollen-specific IgE antibodies
4. The member has experienced therapeutic failure, contraindication, or intolerance to all of the following **(a. and b.)**:
 - a. An intranasal steroid
 - b. One (1) of the following **(i., ii., or iii.)**:
 - i. An oral non-sedating antihistamine
 - ii. An intranasal antihistamine
 - iii. An intranasal anticholinergic agent
5. The member has a concurrent prescription for an epinephrine auto-injector.

D. Odactra

When a benefit, coverage of Odactra may be approved when all of the following criteria are met **(1. through 5.)**:

1. The member is between the ages of 12 and 65 years.
2. The member has a diagnosis of allergic rhinitis due to house dust mites.

3. The member has allergic rhinitis with or without conjunctivitis confirmed by one (1) of the following **(a. or b.)**:
 - a. In vitro testing for IgE antibodies to *D. pteronyssinus* or *D. farinae*
 - b. Skin testing for licensed house dust mite allergen extracts
4. The member has experienced therapeutic failure, contraindication, or intolerance to all of the following **(a. and b.)**:
 - a. An intranasal steroid
 - b. One (1) of the following **(i., ii., or iii.)**:
 - i. An oral non-sedating antihistamine
 - ii. An intranasal antihistamine
 - iii. An intranasal anticholinergic agent
5. The member has a concurrent prescription for an epinephrine auto-injector.

II. Reauthorization

When a benefit, reauthorization of a sublingual immunotherapy may be approved when the following criterion is met **(A.)**:

A. The prescriber attests that the member has experienced improvement in allergy symptoms.

- III. For Medicare Part D beneficiaries, drug(s) addressed in this policy may be approved when used for a medically accepted indication as defined by the Centers for Medicare & Medicaid Services (CMS).

Limitations of Coverage

- I. The member does not have severe, unstable, or uncontrolled asthma.
- II. The member is not using any concomitant sublingual or subcutaneous immunotherapy.
- III. Grastek, Ragwitek, and Oralair treatment should not be initiated during active allergy season.

Authorization Duration

- Medicare Part D Plans: If approved, a 12 month authorization will be granted.

Automatic Approval Criteria

None

References:

1. Oralair [package insert]. Lenoir, NC: GREER Laboratories, Inc.; November 2023.
2. Grastek [package insert]. Horsholm, Denmark: ALK-Abelló, Inc.; September 2022.
3. Ragwitek [package insert]. Horsholm, Denmark: ALK-Abelló, Inc.; September 2022.
4. Odactra [package insert]. Horsholm, Denmark: ALK-Abelló, Inc.; May 2023.
5. Canonica, Giorgio Walter, et al. Sublingual immunotherapy: World Allergy Organization position paper 2013 update. *World Allergy Organ J* 7.1 (2014):
6. Maloney J, et al. Efficacy and safety of grass sublingual immunotherapy tablet, MK-7243: a large randomized controlled trial. *Annals of Allergy, Asthma & Immunology* 112.2 (2014): 146-153.
7. National Allergy Bureau. NAB Pollen Counts. American Academy of Allergy, Asthma & Immunology. Available at: <http://www.aaaai.org/global/nab-pollen-counts.aspx>. Accessed April 23, 2024.
8. Sur DKC, Plesa ML. Treatment of allergic rhinitis. *American Family Physician*. Available at: <https://www.aafp.org/afp/2015/1201/p985.html>. Accessed April 23, 2024.

Pharmacy policies do not constitute medical advice, nor are they intended to govern physicians' prescribing or the practice of medicine. They are intended to reflect the plan's coverage and reimbursement guidelines. Coverage may vary for individual members, based on the terms of the benefit contract.

The plan retains the right to review and update its pharmacy policy at its sole discretion. These guidelines are the proprietary information of the plan. Any sale, copying or dissemination of the pharmacy policies is prohibited; however, limited copying of pharmacy policies is permitted for individual use.