

Sublingual allergen immunotherapy  
(Grastek®, Odactra®, Oralair®, and Ragwitek™)

Place of Service  
Office Administration [1st dose]

HCPCS: J3590

NDC:

Grastek: 00006-4229-30

Odactra: 00006-4202-02

Oralair: 59617-0015-02

Ragwitek: 00006-5420-30,  
00006-5420-54

**Conditions listed in policy (see criteria for details)**

- Allergic rhinitis

**AHFS therapeutic class:** Allergenic extract

**Mechanism of action:** allergen immunotherapy is the administration of specific allergens to which a patient has hypersensitivity to increase allergen tolerance.

**(1) Special Instructions and Pertinent Information**

**First dose of sublingual immunotherapy is covered under the Medical Benefit**, please submit clinical information for prior authorization review via fax.

**Subsequent doses following the first dose are covered under the Pharmacy Prescription Benefit**, please refer cases to Pharmacy Services for prior authorization.

**(2) Prior Authorization/Medical Review is required for the following condition(s)**

**All requests for Grastek®, Odactra®, Oralair®, and Ragwitek™ must be sent for clinical review and receive authorization prior to drug administration or claim payment.**

**Grastek® for allergic rhinitis**

1. Patient is at least 5 years of age, **AND**
2. Being prescribed by an Allergist or Immunologist, **AND**
3. Inadequate response or intolerable side effect to a nasal steroid or medical rationale why all nasal steroids cannot be used, **AND**
4. Documentation indicating positive pollen-specific skin test or pollen-specific IgE test to at least one of the following grasses: Kentucky Blue Grass, Meadow Fescue, Orchard, Perennial Rye, Redtop, Sweet Vernal, or Timothy, **AND**
5. Being used for treatment of allergic rhinitis that is caused by grass allergy, **AND**
6. Medical reason why subcutaneous allergen immunotherapy cannot be used

**Covered Dose**

One tablet on Day 1 of treatment. Subsequent doses are covered under the Pharmacy Prescription benefit if above criteria are met.

**ICD-10:**

J30.1-J30.9, Z91.010-Z91.048

**Odactra® for allergic rhinitis**

1. Patient is at least 18 years of age, **AND**
2. Being prescribed by an Allergist or Immunologist, **AND**
3. Inadequate response or intolerable side effect to a nasal steroid or medical rationale why all nasal steroids cannot be used, **AND**
4. Documentation indicating positive allergy test (skin test or IgE antibodies) specific for dust mites, **AND**
5. Medical reason why subcutaneous allergen immunotherapy cannot be used

**Covered Dose**

One tablet on Day 1 of treatment. Subsequent doses are covered under the Pharmacy Prescription benefit if above criteria are met.

**ICD-10:**

J30.1-J30.9, Z91.010-Z91.048

**Oralair® for allergic rhinitis**

1. Patient is at least 5 years of age, **AND**
2. Being prescribed by an Allergist or Immunologist, **AND**
3. Inadequate response or intolerable side effect to a nasal steroid or medical rationale why all nasal steroids cannot be used, **AND**
4. Documentation indicating positive pollen-specific skin test or pollen-specific IgE test to at least one of the following grasses: Kentucky Blue Grass, Orchard, Perennial Rye, Sweet Vernal, or Timothy, **AND**
5. Being used for treatment of allergic rhinitis that is caused by grass allergies, **AND**
6. Medical reason why subcutaneous allergen immunotherapy cannot be used

**Covered Dose**

One tablet on Day 1 of treatment. Subsequent doses are covered under the Pharmacy Prescription benefit if above criteria are met.

**ICD-10:**

J30.1-J30.9, Z91.010-Z91.048

**Ragwitek™ for allergic rhinitis**

1. Patient is at least 5 years of age, **AND**
2. Being prescribed by an Allergist or Immunologist, **AND**
3. Inadequate response or intolerable side effect to a nasal steroid or medical rationale why all nasal steroids cannot be used, **AND**
4. Patient has allergy to short ragweed pollen, **AND**
5. Documentation indicating positive pollen-specific skin test or pollen-specific IgE test to ragweed pollen, **AND**
6. Medical reason why subcutaneous allergen immunotherapy cannot be used

**Covered Dose**

One tablet on Day 1 of treatment. Subsequent doses are covered under the Pharmacy Prescription benefit if above criteria are met.

**ICD-10:**

J30.1-J30.9, Z91.010-Z91.048

**(3) The following condition(s) DO NOT require Prior Authorization/Preservice**

All requests for Grastek®, Odactra®, Oralair®, and Ragwitek™ must be sent for clinical review and receive authorization prior to drug administration or claim payment.

**(4) This Medication is not medically necessary for the following condition(s)**

Blue Shield's research indicates there is inadequate clinical evidence to support off-label use of this drug for the following conditions (Health and Safety Code 1367.21):

- Concomitant use with other allergen immunotherapy (SC or sublingual)
- Sublingual immunotherapy as a technique of allergy immunotherapy is considered investigational for uses other than those listed in Section (2)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

**(5) Additional Information**

How supplied:

- Grastek®: 2800 Bioequivalent Allergy Units (BAUs) sublingual tablets
- Odactra®: 12 SQ-HDM (house dust mite) sublingual tablets
- Oralair®: 100 IR and 300 IR sublingual tablets
- Ragwitek™: 12 Amb a 1-Unit sublingual tablets

**(6) References**

- AHFS®. Available by subscription at <http://www.lexi.com>
- DrugDex®. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
- Grastek® (Timothy grass pollen allergen extract) [Prescribing information]. Hørsholm, Denmark : ALK-Abelló A/S; 12/2019.
- Greenhawt M, Oppenheimer J, Nelson M, et al. Sublingual immunotherapy: a focused allergen immunotherapy practice parameter update. Ann Allergy Asthma Immunol 2017;118:276-282.
- Odactra (House Dust Mite, Dermatophagoides farina and Dermatophagoides pteronyssinus, Allergen extract) [Prescribing Information]. Hørsholm, Denmark : ALK-Abelló A/S; 8/2019.
- Oralair® (sweet vernal, orchard, perennial rye, Timothy, and Kentucky blue grass mixed pollens allergen extract) [Prescribing information]. Lenoir, NC : Greer Laboratories, Inc. ; 11/2018.
- Ragwitek™ (short ragweed pollen allergen extract) [Prescribing information]. Horshom, Denmark : ALK-Abello Inc. ; 4/2021.

**(7) Policy Update**

Date of initial review: 3Q2022

Date of next review: 3Q2023

Changes from previous policy version:

- New policy

*BSC Drug Coverage Criteria to Determine Medical Necessity  
Reviewed by P&T Committee*