

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. Not used with any other allergen immunotherapy (subcutaneous or sublingual), **AND**
7. 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 12 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. Not used with any other allergen immunotherapy (subcutaneous or sublingual), **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, Z91.038

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. Not used with any other allergen immunotherapy (subcutaneous or sublingual), **AND**
7. 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. Not used with any other allergen immunotherapy (subcutaneous or sublingual), **AND**
7. 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)

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>
- Dykewicz MS, Wallace DV, Amrol DJ, et al. Rhinitis 2020: A practice parameter update. J Allergy Clin Immunol (2020); 146(4): 721-767.
- 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; 1/2023.
- 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 last review: 1Q2023

Date of next review: 1Q2024

Changes from previous policy version:

- No clinical change to policy following routine annual review.

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