blue california
Promise Health Plan

sublingual allergen immunotherapy

Medical Benefit Drug Policy

Sublingual Allergen Immunotherapy

Grastek (Timothy Grass Pollen Allergen Extract)
Odactra (House Dust Mite: Dermatophagoides farinae and Dermatophagoides pteronyssinus)
Oralair (Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass Mixed Pollens Allergen Extract)
Ragwitek (Short Ragweed Pollen Allergen Extract)

Place of Service

Office Administration [1st dose]

Drug Details

USP Category: IMMUNOLOGICAL AGENTS
Mechanism of Action: allergen immunotherapy is the administration of specific allergens to which a patient has hypersensitivity to increase allergen tolerance.

HCPCS:

C9399:Unclassified drugs or biologicals
J3490:Unclassified drugs
J3590:Unclassified biologics

How Supplied:

- Grastek: 2800 Bioequivalent Allergy Units (BAUs) sublingual tablet
  - 3 blister packages of 10 tablets (30 tablets total): NDC 52709-1501-3
- Odactra: 12 SQ-HDM (house dust mite) sublingual tablet
  - 3 blister packages of 10 tablets (30 tablets total): NDC 52709-1701-3
- Oralair: 100 IR and 300 IR sublingual tablet
  - Children and Adolescents Sample Kit (5 to 17 years of age): NDC 59617-0020-1
    - One box of the 100 IR Starter Pack
      Two boxes of the 300 IR Sample Packs
  - Adult Sample Kit (18 to 65 years of age): NDC 59617-0025-1
    - One box of 300 IR Starter Pack
      Two boxes of 300 IR Sample Packs
  - Children and Adolescents Starter Pack (5 to 17 years of age): NDC 59617-0010-1
    - 1 blister pack of three 100 IR tablets
  - Adult Starter Pack (18 to 65 years of age): NDC 59617-0016-1
    - 1 blister pack of three 300 IR tablets
  - Sample Pack: NDC 59617-0015-3
    - 1 blister pack of three 300 IR tablets
  - Commercial Pack: NDC 59617-0015-2
    - 1 blister pack of thirty 300 IR tablets

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- Ragwitek: 12 Amb a 1-Unit sublingual tablet
  - 3 blister packages of 10 tablets (30 tablets total): NDC 52709-1601-3

Condition(s) listed in policy *(see coverage criteria for details)*

- Allergic Rhinitis

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the California Code of Regulations (CCR), Title 22, Section 51303 and 51313 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

First dose of sublingual immunotherapy is covered under the Medical Benefit.

Subsequent doses following the first dose are covered under the Pharmacy Benefit. Please request subsequent doses of this drug from your Pharmacy Benefit.

Coverage Criteria
The following condition(s) require Prior Authorization/Preservice.

Allergic Rhinitis
Grastek
Meets medical necessity if all the following are met:

1. Age is consistent with the FDA approved indication (5 through 65 years of age)
2. Being prescribed by an Allergist or Immunologist
3. Inadequate response or intolerable side effect to a nasal steroid or medical rationale why all nasal steroids cannot be used
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
5. Being used for treatment of allergic rhinitis that is caused by grass allergy
6. Not used with any other allergen immunotherapy (subcutaneous or sublingual)
7. Medical reason why subcutaneous allergen immunotherapy cannot be used

Covered Doses:
Not to exceed 1 tablet given sublingually for 1 day
Subsequent doses are covered under the Pharmacy Benefit.

Coverage Period:

One day

ICD-10:
J30.1-J30.9, Z91.010-Z91.048

Odactra
Meets medical necessity if all the following are met:
1. Age is consistent with the FDA approved indication (5 through 65 years of age)
2. Being prescribed by an Allergist or Immunologist
3. Inadequate response or intolerable side effect to a nasal steroid or medical rationale why all nasal steroids cannot be used
4. Documentation indicating positive allergy test (skin test or IgE antibodies) specific for dust mites
5. Not used with any other allergen immunotherapy (subcutaneous or sublingual)
6. Medical reason why subcutaneous allergen immunotherapy cannot be used

Covered Doses:
Not to exceed 1 tablet given sublingually for 1 day
Subsequent doses are covered under the Pharmacy Benefit.

Coverage Period:
One day

ICD-10:
J30.1-J30.9, Z91.038

Oralair
Meets medical necessity if all the following are met:
1. Age is consistent with the FDA approved indication (5 through 65 years of age)
2. Being prescribed by an Allergist or Immunologist
3. Inadequate response or intolerable side effect to a nasal steroid or medical rationale why all nasal steroids cannot be used
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
5. Being used for treatment of allergic rhinitis that is caused by grass allergies
6. Not used with any other allergen immunotherapy (subcutaneous or sublingual)
7. Medical reason why subcutaneous allergen immunotherapy cannot be used

Covered Doses:
- 5 through 17 years of age: Not to exceed one 100 IR tablet given sublingually for 1 day
- 18 through 65 years of age: Not to exceed one 300 IR tablet given sublingually for 1 day

Subsequent doses are covered under the Pharmacy Benefit.

Coverage Period:
One day

ICD-10:
J30.1-J30.9, Z91.010-Z91.048

Ragwitek
Meets medical necessity if all the following are met:
1. Age is consistent with the FDA approved indication (5 through 65 years of age)
2. Being prescribed by an Allergist or Immunologist
3. Inadequate response or intolerable side effect to a nasal steroid or medical rationale why all nasal steroids cannot be used
4. Patient has allergy to short ragweed pollen
5. Documentation indicating positive pollen-specific skin test or pollen-specific IgE test to ragweed pollen
6. Not used with any other allergen immunotherapy (subcutaneous or sublingual)
7. Medical reason why subcutaneous allergen immunotherapy cannot be used

Covered Doses:
Not to exceed 1 tablet given sublingually for 1 day
Subsequent doses are covered under the Pharmacy Benefit.

Coverage Period:
One day

ICD-10:
J30.1-J30.9, Z91.010-Z91.048

References

1. Dykewicz MS, Wallace DV, Amrol DJ, et al. Rhinitis 2020: A practice parameter update. J Allergy Clin Immunol (2020); 146(4): 721-767.
2. Grastek (Timothy grass pollen allergen extract) Prescribing Information. ALK-Abelló A/S, Hørsholm, Denmark: 12/2019.
3. 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.
4. Odactra (House Dust Mite, Dermatophagoides farina and Dermatophagoides pteronyssinus, Allergen extract) Prescribing Information. ALK-Abelló A/S, Hørsholm, Denmark: 2/2025.
5. Oralair (sweet vernal, orchard, perennial rye, Timothy, and Kentucky blue grass mixed pollens allergen extract) Prescribing Information. Greer Laboratories, Lenoir, NC: 11/2018.

6. Ragwitek (short ragweed pollen allergen extract) prescribing information. ALK-Abelló A/S, Hørsholm, Denmark: 4/2021.

Review History

Date of Last Annual Review: 2Q2026

Changes from previous policy version:

- No clinical change to policy following annual review.

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee