UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2029-14
Program	Prior Authorization/Medical Necessity - Sublingual Immunotherapy (SLIT)
Medication	Sublingual Immunotherapy (SLIT) - Grastek (Timothy grass pollen allergen extract), Odactra (*Dermatophagoides farinae/Dermatophagoides pteronyssinus* allergen extract), Oralair (Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass Mixed Pollens allergen extract), Ragwitek (Short Ragweed Pollen allergen extract)
P&T Approval Date	5/2014, 5/2015, 4/2016, 4/2017, 3/2018, 3/2019, 3/2020, 3/2021, 9/2021, 3/2022, 3/2023, 3/2024
Effective Date	6/1/2024

1. Background:

The sublingual immunotherapy (SLIT) medications are indicated for patients who have symptoms of allergic rhinitis with natural exposure to allergens and who demonstrate specific IgE antibodies to the relevant allergen. Grastek (Timothy grass pollen allergen extract) and Oralair (Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass Mixed Pollens allergen extract) are indicated for patients with grass pollen-induced allergic rhinitis, Ragwitek (short ragweed pollen allergen extract) is indicated for ragweed pollen-induced allergic rhinitis and Odactra (*Dermatophagoides farinae/Dermatophagoides pteronyssinus* allergen extract), is indicated for house dust mite (HDM)-induced allergic rhinitis.

Candidates for allergen immunotherapy are patients whose symptoms are not adequately controlled by medications, and avoidance measures have been ineffective. In addition, patients experiencing unacceptable adverse effects of medications or who wish to reduce the long-term use of medications may also be candidates for immunotherapy.

2. Coverage Criteria[a]:

A. Grastek

1. **Initial Authorization**

a. **Grastek** will be approved based on **all** of the following:

(1) Diagnosis of moderate to severe grass pollen-induced allergic rhinitis defined by symptoms severe enough to interfere with quality of life (e.g., sleep disturbances; impairment of daily, sport, or leisure activities; impairment of school or work performance)

-AND-

(2) Diagnosis confirmed by **one** of the following:

a. Positive skin test to Timothy grass or cross-reactive grass pollens (e.g.,

Sweet Vernal, Orchard/Cocksfoot, Perennial Rye, Kentucky blue/June grass, Meadow Fescue, or Redtop)

b. *in vitro* testing for pollen-specific IgE antibodies for Timothy grass or cross-reactive grass pollens (e.g., Sweet Vernal, Orchard/Cocksfoot, Perennial Rye, Kentucky blue/June grass, Meadow Fescue, or Redtop)

-AND-

(3) Treatment is started or will be started at least 12 weeks before the beginning of the grass pollen season

-AND-

(4) History of failure, contraindication, or intolerance to **two** of the following:

a. oral antihistamine [e.g. cetirizine (Zyrtec)]
b. intranasal antihistamine [e.g. azelastine (Astelin)]
c. intranasal corticosteroid [e.g. fluticasone (Flonase)]
d. leukotriene inhibitor [e.g. montelukast (Singulair)]

-AND-

(5) Not received in combination with similar cross-reactive grass pollen immunotherapy (e.g., Oralair)

-AND-

(6) Patient does not have unstable and/or uncontrolled asthma

-AND-

(7) Prescribed by or in consultation with a specialist in allergy and immunology

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Grastek** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Grastek therapy

Authorization will be issued for 12 months.

B. Oralair

1. **Initial Authorization**

a. **Oralair** will be approved based on **all** of the following:

(1) Diagnosis of moderate to severe grass pollen-induced allergic rhinitis defined by

symptoms severe enough to interfere with quality of life (e.g., sleep disturbances; impairment of daily, sport, or leisure activities; impairment of school or work performance)

-AND-

(2) Diagnosis confirmed by **one** of the following:

a. Positive skin test to any of the five grass species contained in Oralair [(i.e., Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue grass mixed pollens) or cross-reactive grass pollens (e.g., Cocksfoot, Meadow Fescue, or Redtop)]
b. *in vitro* testing for pollen-specific IgE antibodies for any of the five grass species contained in Oralair [(i.e., Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue grass mixed pollens) or cross-reactive grass pollens (e.g., Cocksfoot, Meadow Fescue, or Redtop)]

-AND-

(3) Treatment is started or will be started at least 4 months before the beginning of the grass pollen season

-AND-

(4) History of failure, contraindication, or intolerance to **two** of the following:

a. oral antihistamine [e.g. cetirizine (Zyrtec)]
b. intranasal antihistamine [e.g. azelastine (Astelin)]
c. intranasal corticosteroid [e.g. fluticasone (Flonase)]
d. leukotriene inhibitor [e.g. montelukast (Singulair)]

-AND-

(5) Not received in combination with similar cross-reactive grass pollen immunotherapy (e.g., Grastek)

-AND-

(6) Patient does not have unstable and/or uncontrolled asthma

-AND-

(7) Prescribed by or in consultation with a specialist in allergy and immunology

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Oralair** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Oralair therapy

Authorization will be issued for 12 months.

C. Ragwitek

1. **Initial Authorization**

a. **Ragwitek** will be approved based on **all** of the following:

(1) Diagnosis of moderate to severe short ragweed pollen-induced allergic rhinitis defined by symptoms severe enough to interfere with quality of life (e.g., sleep disturbances; impairment of daily, sport, or leisure activities; impairment of school or work performance)

-AND-

(2) Diagnosis confirmed by **one** of the following:

a. Positive skin test to short ragweed pollen
b. *in vitro* testing for pollen-specific IgE antibodies for short ragweed pollen

-AND-

(3) Treatment is started or will be started at least 12 weeks before the beginning of the short ragweed pollen season

-AND-

(4) History of failure, contraindication, or intolerance to **two** of the following:

a. oral antihistamine [e.g. cetirizine (Zyrtec)]
b. intranasal antihistamine [e.g. azelastine (Astelin)]
c. intranasal corticosteroid [e.g. fluticasone (Flonase)]
d. leukotriene inhibitor [e.g. montelukast (Singulair)]

-AND-

(5) Patient does not have unstable and/or uncontrolled asthma

-AND-

(6) Prescribed by or in consultation with a specialist in allergy and immunology

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Ragwitek** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Ragwitek therapy

Authorization will be issued for 12 months.

D. Odactra

1. **Initial Authorization**

a. **Odactra** will be approved based on **all** of the following:

(1) Diagnosis of house dust mite (HDM)-induced allergic rhinitis

-AND-

(2) Diagnosis confirmed by **one** of the following:

(a) Positive skin test to licensed house dust mite allergen extracts
(b) *in vitro testing* for IgE antibodies to *Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* house dust mites

-AND-

(3) History of failure, contraindication, or intolerance to **two** of the following:

a. oral antihistamine [e.g. cetirizine (Zyrtec)]
b. intranasal antihistamine [e.g. azelastine (Astelin)]
c. intranasal corticosteroid [e.g. fluticasone (Flonase)]
d. leukotriene inhibitor [e.g. montelukast (Singulair)]

-AND-

(4) Patient does not have unstable and/or uncontrolled asthma

-AND-

(5) Prescribed by or in consultation with a specialist in allergy and immunology

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Odactra** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Odactra therapy

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class
- Supply limits and/or Notification may be in place.

4. References:

1. Grastek® [package insert]. Blagrove Swindon Wiltshire, UK: Catalent Pharma Solutions Limited; September 2022.
2. Oralair® [package insert]. Lenoir, NC: Greer Laboratories, Inc.: September 2022.
3. Ragwitek® [package insert]. Blagrove Swindon, Wiltshire, UK: Catalent Pharma Solutions Limited; September 2022.
4. Odactra® [package insert]. Blagrove Swindon, Wiltshire, UK: Catalent Pharma Solutions Limited: May 2023.
5. Cox, L, Nelson, H, Lockey, R, et al. Allergen immunotherapy: A practice parameter third update. American Academy of Allergy, Asthma & Immunology. December 2010.
6. Treatment of seasonal allergic rhinitis: An evidence-based focused 2017 guideline update. Dykewicz MS, Wallace DV, Baroody F, et.al. *Ann Allergy Asthma Immunol*. 2017 Dec;119(6):489-511.e41
7. Sublingual immunotherapy: A focused allergen immunotherapy practice parameter update. Greenhawt M, Oppenheimer J, Nelson M, et.al. *Ann Allergy Asthma Immunol*. 2017 Mar;118(3):276-82.e2.

Program	Prior Authorization/Medical Necessity – Sublingual Immunotherapy (SLIT)
Change Control	
Date	Change
5/2014	New Program
5/2015	Administrative changes and updates to references.
4/2016	Removed SCIT requirement, removed allergen avoidance, updated specialist prescriber requirement. References updated.
7/2016	Added Indiana and West Virginia coverage information.
11/2016	Administrative change. Added California coverage information.
4/2017	Odactra added to criteria. State mandate reference language updated.
3/2018	Annual review. References updated.
3/2019	Annual review with administrative changes. Modified symptomatic asthma to severe, unstable and/or uncontrolled asthma. Added statement regarding use of automated processes and updated references.
3/2020	Annual review. Updated references.
3/2021	Annual review. Updated references.
9/2021	Added clarification around moderate to severe allergic rhinitis based on American Academy of Allergy, Asthma & Immunology guidelines.
3/2022	Updated references.
3/2023	Annual review. Updated references.
3/2024	Annual review. Updated references.