UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Sublingual Immunotherapy (SLIT)

Program	Prior Authorization- 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)
Issue Date	5/2014
Pharmacy and Therapeutics Approval Date	3/2018
Effective Date	5/2018

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. <u>Grastek</u>

1. <u>Initial Authorization</u>

a. **Grastek** will be approved based on **<u>all</u>** of the following:

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

-AND-

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

a. Positive skin test to Timothy grass or cross-reactive grass pollens (eg, 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 symptomatic 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

-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 symptomatic 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

-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 symptomatic 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 symptomatic 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.

3. References:

1. Grastek® prescribing information. Catalent Pharma Solutions Limited, Blagrove Swindon, Wiltshire, UK. April 2017.
2. Oralair® prescribing information. Greer Laboratories, Inc. Lenoir, NC. January 2016.
3. Ragwitek® prescribing information. Catalent Pharma Solutions Limited, Blagrove Swindon, Wiltshire, UK. April 2017.
4. Ocactra® prescribing information. Catalent Pharma Solutions Limited, Blagrove,Swindon, Wiltshire, UK. April 2017.
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, Bernstein J, Craig T, Finegold I,

Huang F, Larenas-Linnemann D, Meltzer E, Steven G, Bernstein DI, Blessing-Moore J, Dinakar C, Greenhawt M, Horner CC, Khan DA, Lang D, Oppenheimer J, Portnoy JM, Randolph CR, Rank MA; Workgroup Chair and Cochair, Dykewicz MS, Wallace DV. 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, Nelson H, Lockey R, Lieberman P, Nowak-Wegrzyn A, Peters A, Collins C, Bernstein DI, Blessing-Moore J, Khan D, Lang D, Nicklas RA, Portnoy JM, Randolph CR, Schuller DE, Spector SL, Tilles SA, Wallace D. Ann Allergy Asthma Immunol. 2017 Mar;118(3):276-282.e2.
8. Wallace, DV, Dykewicz, MS, et al. The diagnosis and management of rhinitis: An updated practice parameter. American Academy of Allergy, Asthma & Immunology. August 2008.

Program	Program Type- Prior Authorization
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.
4/2017	Odactra added to criteria. Added examples of drugs to step through. Updated policy template.
3/2018	Annual review. Updated background and references.