

Pharmacy Policy

Sublingual Immunotherapy (SLIT) Medications

Policy Number: 9.104

Version Number: 2

Version Effective Date: 1/1/2022

<p>Product Applicability <input type="checkbox"/> All Plan+ Products</p>	
<p>Well Sense Health Plan</p> <p><input type="checkbox"/> New Hampshire Medicaid</p>	<p>Boston Medical Center HealthNet Plan</p> <p><input checked="" type="checkbox"/> MassHealth - MCO</p> <p><input checked="" type="checkbox"/> MassHealth - ACO</p> <p><input type="checkbox"/> Qualified Health Plans/ConnectorCare/Employer Choice Direct</p> <p><input type="checkbox"/> Senior Care Options</p>

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Products Affected:

- Ragwitek (short ragweed pollen allergen extract)
- Grastek (timothy grass pollen allergen extract)
- Oralair (sweet vernal, orchard, perennial rye, timothy, and Kentucky Blue Grass mixed pollen allergen extracts)
- Odactra (house dust mites allergen extract)

The Plan may authorize coverage of the above products for members meeting the following criteria:

Covered Use	All FDA approved indications not otherwise excluded
Exclusion Criteria	None
Required Medical Information	<p>Ragwitek</p> <p>1. A diagnosis of ragweed pollen-induced allergic rhinitis confirmed by either positive skin test or</p>

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positive *in vitro* testing for pollen-specific IgE antibodies for short ragweed pollen; **AND**

2. **One** of the following:
 - a. An inadequate response, intolerance to 2 trials each of a nasal corticosteroid in combination with a non-sedating antihistamine; **OR**
 - b. An inadequate response, intolerance to trials of 2 non-sedating antihistamines, and documented contraindication to use of nasal corticosteroids; **OR**
 - c. An inadequate response, intolerance to trials of 2 nasal corticosteroids, and documented contraindication to use of non-sedating antihistamines; **AND**
3. A documented concurrent prescription for an auto-injectable epinephrine product; **AND**
4. Treatment will be initiated at least 12 weeks (no later than mid-May) before the expected onset of ragweed pollen season and continued throughout the season.

Grastek

1. A diagnosis of Timothy grass pollen-induced allergic rhinitis confirmed by either positive skin test or positive *in vitro* testing for pollen-specific IgE antibodies for Timothy grass or cross-reactive grass pollen; **AND**
2. **One** of the following:
 - a. An inadequate response, intolerance to 2 trials each of a nasal corticosteroid in combination with a non-sedating antihistamine; **or**
 - b. An inadequate response, intolerance to trials of 2 non-sedating antihistamines, and documented contraindication to use of nasal corticosteroid; **or**
 - c. An inadequate response, intolerance to trials of 2 nasal corticosteroids, and documented contraindication to use of non-sedating antihistamines; **AND**
3. A documented concurrent prescription for an auto-injectable epinephrine product; **AND**
4. Treatment will be initiated at least 12 weeks (no later than mid-February) before the expected onset of grass pollen season and continued throughout the season.

Oralair

1. A diagnosis of grass pollen-induced allergic rhinitis confirmed by either positive skin test or positive *in vitro* testing for pollen-specific IgE antibodies for any of the five grass species: sweet vernal, orchard, perennial rye, timothy, or Kentucky blue grass; **AND**
2. **One** of the following:
 - a. An inadequate response, intolerance to 2 trials each of a nasal corticosteroid in combination with a non-sedating antihistamine; **or**
 - b. An inadequate response, intolerance to trials of 2 non-sedating antihistamines, and documented contraindication to use of nasal corticosteroid; **or**
 - c. An inadequate response, intolerance to trials of 2 nasal corticosteroids, and documented contraindication to use of non-sedating antihistamines; **AND**

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	<p>3. A documented concurrent prescription for an auto-injectable epinephrine product; AND</p> <p>4. Treatment will be initiated at least 4 months (no later than January 1th) before the expected onset of each grass pollen season and continued throughout the season.</p> <p>Odactra</p> <p>1. A diagnosis of house dust mite-induced allergic rhinitis confirmed by either positive skin test or positive in vitro testing IgE antibodies to <i>Dermatophagoides farina</i> or <i>Dermatophagoises pteronyssinus</i>; AND</p> <p>2. One of the following:</p> <p>a. An inadequate response, intolerance to 2 trials each of a nasal corticosteroid in combination with a non-sedating antihistamine; or</p> <p>b. An inadequate response, intolerance to trials of 2 non-sedating antihistamines, and documented contraindication to use of nasal corticosteroid; or</p> <p>c. An inadequate response, intolerance to trials of 2 nasal corticosteroids, and documented contraindication to use of non-sedating antihistamines; AND</p> <p>3. A documented concurrent prescription for an auto-injectable epinephrine product</p>
Age Restriction	<p>Ragwitek: Age is between 5 and 65 years old</p> <p>Grastek: Age is between 5 and 65 years old</p> <p>Oralair: Age is between 5 and 65 years old</p> <p>Odactra: Age is between 18 and 65 years old</p>
Prescriber Restriction	Prescribed by or in consultation with an allergist or immunologist
Coverage Duration	<p>Ragwitek: Approval duration from May 1st through October 31st</p> <p>Grastek: 12 months</p> <p>Oralair: Approval duration from December 1st through August 31st</p> <p>Odactra: 4 months</p>
Other criteria	None

Clinical Background Information and References

1. Product Information. Ragwitek™. ALK-Abello A/S, Horsholm, Denmark May 2021.
2. Product Information. Grastek®. Merck & Co., Inc. Whitehouse Station, NH. June 2014.
3. Product Information. Oralair®. Stallergenes S.A. Antony, France. November 2018.
4. Creticos PS. Sublingual immunotherapy for allergic rhinoconjunctivitis and asthma. UptoDate online. Accessed February 2016.
5. Aboshady OA and Elghanam KM. Sublingual Immunotherapy in Allergic Rhinitis: Efficacy, Safety, Adherence and Guidelines. Clin Exp Otorhinolaryngol. 2014 Dec;7(4):241-249.
6. Seidman M D et al. Clinical Practice Guideline: Allergic Rhinitis Executive Summary. Otolaryngol Head Neck Surg. 2015 Feb;152(2):197-206.
7. National Allergy Bureau. <http://www.aaaai.org/global/nab-pollen-counts.aspx>. Accessed February 2015.
8. Pongdee T. Ragweed Plants Packed with Pollen. August, 2011. Available: <https://www.aaaai.org/Aaaai/media/MediaLibrary/PDF%20Documents/Libraries/EL-ragweed-patient.pdf>. Accessed February 2015.
9. Product Information. Odactra™. Catalent Pharma Solutions Limited. Swindon, Wiltshire, UK. March 2017

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Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	Summary of Revisions	Revision Effective Date	Approved by
12/1/2020	9.053 SLIT Medications Policy retired, new policy created	1/1/2021	P&T Committee
8/12/2021	Annual P&T Review, updated FDA approved age ranges for Ragwitek and Oralair, added prescriber restriction for allergist or immunologist	1/1/2022	P&T Committee

Next Review Date

8/2022

Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

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