

Medical Policy



An independent licensee of the
Blue Cross Blue Shield Association

Title: Oral Immunotherapy Agents

- Prime Therapeutics will review Prior Authorization requests.

Prior Authorization Form:

<http://www.bcbsks.com/CustomerService/Forms/pdf/PriorAuth-6344KS-OIMN.pdf>

Link to Drug List (Formulary):

<http://www.bcbsks.com/drugs/>

Professional

Original Effective Date: July 23, 2004
Revision Date(s): June 7, 2013;
August 18, 2014; November 1, 2014;
April 14, 2015; October 1, 2015;
April 15, 2016; May 15, 2017;
April 1, 2018
Current Effective Date: April 1, 2018

Institutional

Original Effective Date: July 23, 2004
Revision Date(s): June 7, 2013;
August 18, 2014; November 1, 2014;
April 14, 2015; October 1, 2015;
April 15, 2016; May 15, 2017;
April 1, 2018
Current Effective Date: April 1, 2018

State and Federal mandates and health plan member contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. To verify a member's benefits, contact [Blue Cross and Blue Shield of Kansas Customer Service](#).

The BCBSKS Medical Policies contained herein are for informational purposes and apply only to members who have health insurance through BCBSKS or who are covered by a self-insured group plan administered by BCBSKS. Medical Policy for FEP members is subject to FEP medical policy which may differ from BCBSKS Medical Policy.

The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents of Blue Cross and Blue Shield of Kansas and are solely responsible for diagnosis, treatment and medical advice.

If your patient is covered under a different Blue Cross and Blue Shield plan, please refer to the Medical Policies of that plan.

DESCRIPTION

The intent of the Oral Immunotherapy Agents Prior Authorization (PA) program is to ensure appropriate selection of patients for treatment according to product labeling and guidelines. The PA defines appropriate use based on FDA approved package information and current clinical guidelines published by the Joint Task Force on Practice Parameters

for Allergy and Immunology. The PA defines appropriate use as immunotherapy of allergic rhinitis in patients who have a positive skin test or IgE specific antibodies who have tried at least two traditional allergy medications, one of which is a nasal corticosteroid or have a documented intolerance, FDA labeled contraindication, or hypersensitivity to traditional treatments. PA criteria also include documentation of provider's specialty (allergy or immunology), documentation that the patient is to receive the first dose under direct supervision (30 minutes) of that provider and that the patient has epinephrine injection available at home, and initiation of therapy at the required interval before the pollen season. Appropriate dosing based on FDA labeling will be included with a quantity limit of one tablet per day. Requests for oral immunotherapy agents will be reviewed when patient-specific documentation has been provided.

Target Drugs

Grastek® (Timothy Grass Pollen Allergen Extract)

Odactra Dermatophagoides farinae and 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)

FDA Labeled Indications^{1-3,10}

Product	Indication(s)	Dosage and Administration*
Grastek® (Timothy Grass Pollen Allergen Extract) Sublingual tablet – 2800 Bioequivalent Allergy Unit (BAU)	Treatment of grass pollen-induced allergic rhinitis with or without conjunctivitis confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for Timothy grass or cross-reactive grass pollens. Grastek is approved for use in persons 5 through 65 years of age.	Take one tablet daily; place tablet under the tongue and allow it to remain there until completely dissolved. Do not take with food. Initiate treatment at least 12 weeks before the expected onset of each grass pollen season and continue throughout the season. For sustained effectiveness Grastek may be taken daily for 3 consecutive years (including intervals between grass pollen seasons). Administer the first dose under the supervision of a physician with experience in the diagnosis and treatment of allergic diseases. Observe patients in the office for at least 30 minutes following the initial dose.
Odactra™ (House Dust Mite: Dermatophagoides farinae and Dermatophagoides pteronyssinus Allergen Extract)	Immunotherapy for house dust mite (HDM)-induced allergic rhinitis, with or without conjunctivitis, confirmed by in vitro testing for IgE antibodies to Dermatophagoides farinae or	Take one tablet daily; place tablet under the tongue where it will dissolve within 10 seconds. Do not swallow for at least 1 minute. Do not take with food or beverage.

Product	Indication(s)	Dosage and Administration*
<p>Sublingual tablet - 12 SQ-HDM biological potency</p>	<p>Dermatophagoides pteronyssinus house dust mites, or skin testing to licensed house dust mite allergen extracts. Odactra is approved for use in adults 18 through 65 years of age.</p>	<p>Administer the first dose under the supervision of a physician with experience in the diagnosis and treatment of allergic diseases. Observe the patient for at least 30 minutes following the initial dose.</p>
<p>Oralair® (Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue grass Mixed Pollens Allergen extract)</p> <p>Sublingual tablet – 100 IR 300 IR (Index of Reactivity)</p>	<p>Treatment of grass pollen-induced allergic rhinitis with or without conjunctivitis confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for any of the five grass species contained in this product. Oralair is approved for use in persons 10 through 65 years of age.</p>	<p>Adults (age 18-65) Take one tablet (300 IR) daily</p> <p>Children, Adolescents (age 10-17) Increase dose over the first few days: Day 1 – 100 IR Day 2 – 100 IR x 2 Day 3 and following – 300 IR</p> <p>Place tablet under the tongue and allow it to remain there until completely dissolved. Do not take with food. Administer Oralair to children under adult supervision.</p> <p>Initiate treatment at least 4 months before the expected onset of each grass pollen season and continue throughout the season.</p> <p>Administer the first dose under the supervision of a physician with experience in the diagnosis and treatment of severe allergic reactions. Observe the patient for at least 30 minutes.</p>
<p>Ragwitek® (Short Ragweed Pollen Allergen Extract)</p> <p>Sublingual tablet – 12 Amb a 1-Unit</p>	<p>Treatment of short ragweed pollen-induced allergic rhinitis, with or without conjunctivitis, confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for short ragweed pollen. Ragwitek is approved for use in adults 18 through 65 years of age.</p>	<p>Take one tablet daily; place tablet under the tongue and allow it to remain there until completely dissolved. Do not take with food.</p> <p>Initiate treatment at least 12 weeks before the expected onset of ragweed pollen season and continue throughout the season.</p> <p>Administer the first dose in a healthcare setting under the supervision of a physician with experience in the diagnosis and treatment of allergic diseases. After receiving the first dose,</p>

Product	Indication(s)	Dosage and Administration*
		observe the patient for at least 30 minutes to monitor for signs or symptoms of a severe systemic or a severe local allergic reaction. If the patient tolerates the first dose, the patient may take subsequent doses at home.

* Administer the first dose of these products in a healthcare setting under the supervision of a physician with experience in the diagnosis and treatment of allergic diseases. After receiving the first dose of the product, observe the patient for at least 30 minutes to monitor for signs or symptoms of a severe systemic or a severe local allergic reaction. If the patient tolerates the first dose, the patient may take subsequent doses at home.^{1-3,10}

POLICY

PRIOR AUTHORIZATION AND QUANTITY LIMIT CRITERIA FOR APPROVAL

A. **Grastek, Odactra, Oralair, or Ragwitek** will be approved when ALL of the following are met:

1. The patient has a diagnosis of allergic rhinitis, with or without conjunctivitis
AND
2. The patient’s diagnosis is confirmed with ONE of the following:
 - a. Positive skin test to ONE of the pollen extracts included in the requested agent (Grastek, Oralair, or Ragwitek) or licensed house dust mite allergen (Odactra) **OR**
 - b. IgE specific antibodies to ONE of the extracts included in the requested agent
 - i. Grastek: Timothy grass or cross-reactive grass
 - ii. Odactra: Dermatophagoides farinae or Dermatophagoides pteronyssinus
 - iii. Oralair: Sweet vernal, orchard, perennial rye, Timothy, or Kentucky blue grass
 - iv. Ragwitek: Short Ragweed
- AND**
3. The patient is within the FDA labeled age range:
 - a. Grastek: between the ages of 5 and 65
 - b. Odactra: between the ages of 18 and 65
 - c. Oralair: between the ages of 10 and 65
 - d. Ragwitek: between the ages of 18 and 65
- AND**
4. The prescriber has expertise in allergy or immunology or has consulted with an expert in allergy or immunology
AND
5. ONE of the following:
 - a. The patient has tried and failed at least two traditional allergy medications, one of which was an intranasal corticosteroid
- OR**

- b. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to at least two standard allergy therapies, one of which was an intranasal corticosteroid
- AND**
- 6. The patient is not currently using subcutaneous injectable immunotherapy
- AND**
- 7. The patient is not currently taking a beta blocker
- AND**
- 8. If the requested agent is Grastek, Oralair, or Ragwitek: The product will be started, or has already been started, 3 to 4 months before the expected onset of the applicable pollen season
- AND**
- 9. The first dose is given in the clinic/hospital under direct supervision from the provider for a period of at least 30 minutes
- AND**
- 10. The patient has been prescribed epinephrine auto-injector for at home emergency use
- AND**
- 11. The patient does not have any FDA labeled contraindications to the requested agent
- AND**
- 12. ONE of the following:
 - a. The requested quantity (dose) is less than or equal to the program quantity limit
- OR**
- b. ALL of the following
 - i. The requested quantity (dose) is above the set limit
- AND**
- ii. ONE of the following
 - 1) BOTH of the following
 - a) The requested quantity (dose) requested is below the FDA labeled dose
- AND**
- b) The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the limit
- OR**
- 2) BOTH of the following
 - a) The requested quantity (dose) requested is above the FDA labeled dose
- AND**
- b) The prescriber has submitted documentation in support of therapy with a higher dose for the intended diagnosis

Length of approval: 12 months

- B. Sublingual immunotherapy as a technique of allergy immunotherapy is considered **experimental / investigational** for all other uses.

FDA Labeled Contraindications

Agent	Contraindications
Grastek	<ol style="list-style-type: none"> 1. Severe, unstable or uncontrolled asthma 2. History of any severe systemic allergic reaction 3. History of any severe local reaction to sublingual allergen immunotherapy 4. History of eosinophilic esophagitis 5. Hypersensitivity to any of the inactive ingredients contained in this product
Odactra	<ol style="list-style-type: none"> 1. Severe, unstable or uncontrolled asthma 2. History of any severe systemic allergic reaction or any severe local reaction to sublingual allergen immunotherapy 3. A history of eosinophilic esophagitis 4. Hypersensitivity to any of the inactive ingredients contained in this product
Oralair	<ol style="list-style-type: none"> 1. Severe, unstable or uncontrolled asthma 2. History of any severe systemic allergic reaction 3. History of any severe local reaction to sublingual allergen immunotherapy 4. History of eosinophilic esophagitis 5. Hypersensitivity to any of the inactive ingredients contained in this product
Ragwitek	<ol style="list-style-type: none"> 1. Severe, unstable or uncontrolled asthma 2. History of any severe systemic allergic reaction 3. History of any severe local reaction to sublingual allergen immunotherapy 4. History of eosinophilic esophagitis 5. Hypersensitivity to any of the inactive ingredients contained in this product

Quantity Limits for Target Agents			
Brand (generic)	GPI	Multisource Code	Quantity Limit
Grastek (Timothy Grass Pollen Allergen Extract)			
Tablet, 2800 BAUs (Bioequivalent Allergy Units)	20100048000740	M, N, O, or Y	1 tablet/day
Odactra (Dermatophagoides farinae and Dermatophagoides pteronyssinus Allergen Extract)			
Tablet, 12 SQ-HDM biological potency	20109902220740	M, N, O, or Y	1 tablet/day
Oralair (Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass Mixed Pollens Allergen Extract)			
Tablet, 300 IR (index of reactivity)	20109905200730	M, N, O, or Y	1 tablet/day
Children/Adolescent Starter Pack	20109905200720	M, N, O, or Y	1 pack/180 days
Ragwitek (Short Ragweed Pollen Allergen Extract)			
Tablet, 12 Amb a 1-U (Amb a 1-Unit)	20100060200720	M, N, O, or Y	1 tablet/day

RATIONALE

Guidelines

Conventional pharmacotherapy for allergic rhinitis include antihistamines, nasal corticosteroids, oral corticosteroids, and leukotriene inhibitors. Intranasal corticosteroids are considered the most effective conventional pharmacotherapy.⁴

Guidelines consider both sublingual immunotherapy (SLIT) and subcutaneous immunotherapy (SCIT) effective treatments for adults and children with rhinosinusitis that does not respond to conventional pharmacotherapy and allergen avoidance measures. Immunotherapy may be considered in asthma patients with a clear relationship of asthma symptoms with allergens such as asthma with allergic rhinoconjunctivitis, however there is no clear or consistent evidence that lung function improves.⁵⁻⁹

Safety^{1-3,10}

All four oral immunotherapy agents carry the same boxed warning:

- Can cause life-threatening allergic reactions such as anaphylaxis and severe laryngopharyngeal edema/restriction.
- Do not administer to patients with severe, unstable or uncontrolled asthma.
- Observe patients in the office for at least 30 minutes following the initial dose.
- Prescribe auto-injectable epinephrine, instruct and train patients on its appropriate use, and instruct patients to seek immediate medical care upon its use.
- May not be suitable for patients with certain underlying medical conditions that may reduce their ability to survive a serious allergic reaction.
- May not be suitable for patients who may be unresponsive to epinephrine or inhaled bronchodilators, such as those taking beta-blockers.

All four oral immunotherapy agents carry the same contraindications:

- Severe, unstable or uncontrolled asthma.
- History of any severe systemic allergic reaction or any severe local reaction to sublingual allergen immunotherapy.
- A history of eosinophilic esophagitis.
- Hypersensitivity to any of the inactive ingredients contained in this product.

Grastek, Odactra, Oralair, and Ragwitek have not been studied in subjects who are receiving concomitant allergen immunotherapy. Concomitant dosing with other allergen immunotherapy may increase the likelihood of local or systemic adverse reactions to either subcutaneous or sublingual allergen immunotherapy.^{1,2,3,10}

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CPT/HCPCS

95199 Unlisted allergy / clinical immunologic service or procedure
J3490 Unclassified drugs

There are no specific HCPCS codes for the drugs listed in this policy.

- The unlisted CPT code 95199 should be used.
- CPT codes for allergen immunotherapy are specific to parenteral administration and should not be used for sublingual immunotherapy.

ICD-10 Diagnoses

J30.1 Allergic rhinitis due to pollen

REVISIONS

06-07-2013	Policy added to the bcbsks.com web site.						
08-18-2014	<p>Description section updated</p> <p>In Policy section:</p> <ul style="list-style-type: none"> ▪ Revised policy from experimental / investigational to medically necessary adding, "Sublingual immunotherapy using Oralair®, Grastek®, or Ragwitek® may be considered medically necessary, when used according to FDA-labelling, for the treatment of pollen-induced allergic rhinitis when the following conditions are met: <ol style="list-style-type: none"> 1. Patient has a history of rhinitis or rhinoconjunctivitis symptoms related to grass or short ragweed pollen exposure. 2. Patient has a documented positive pollen-specific skin test or pollen-specific immunoglobulin E (IgE) test (see Policy Guidelines section). 3. Patient's symptoms are not adequately controlled by appropriate pharmacotherapy (see Policy Guidelines section)." <ul style="list-style-type: none"> ▪ Revised E/I statement adding "for all other uses" to read, "Sublingual immunotherapy as a technique of allergy immunotherapy is considered experimental / investigational for all other uses." ▪ Added Policy Guidelines: "For Oralair®, Grastek®, or Ragwitek®(1-3): <u>Documentation of Allergy</u> Allergy must be confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies to the species contained in the product or, for Grastek®, Timothy grass pollen extract, to cross-reactive species. <u>Contraindications</u> Contraindications include severe, unstable or uncontrolled asthma; history of any severe local reaction, or any severe systemic allergic reaction to SLIT; and for Grastek® and Ragwitek®, history of eosinophilic esophagitis. <u>Administration and Dose</u> 1. Prescribing information includes a black box warning for severe allergic reactions including anaphylaxis. Patients must be prescribed an epinephrine auto-injector and be trained on how to use it. 2. Treatment should begin 12 weeks (16 weeks for Oralair®) before the expected onset of the allergy-inducing pollen season. Each product is dosed once daily and continued throughout the pollen season (preseasonal dosing). 3. The first dose is administered under the supervision of a physician experienced in diagnosing and treating severe allergic reactions. Subsequent doses may be taken at home. 4. All 3 agents are dosed once daily. 5. For Oralair®, dose titration is required in patients 10 to 17 years of age. Titration can be completed over 3 days at home (after the first dose) according to the schedule in Table 1. In patients between 18 to 65 years, no dose titration is needed; treatment is initiated at the maintenance dose of 300 IR (index of reactivity). 6. Grastek® and Ragwitek® both are initiated at the maintenance dose (2800 BAU [bioequivalent allergy unit] and 12 Amb a 1 unit, respectively). Table 1. Oralair® Dosing in Patients Age 10-17 Years(1) <table border="1" data-bbox="391 1791 1455 1854"> <thead> <tr> <th data-bbox="391 1791 743 1822">Day 1</th> <th data-bbox="743 1791 1092 1822">Day 2</th> <th data-bbox="1092 1791 1455 1822">Day 3 and Following</th> </tr> </thead> <tbody> <tr> <td data-bbox="391 1822 743 1854">100 IR</td> <td data-bbox="743 1822 1092 1854">2 x 100 IR</td> <td data-bbox="1092 1822 1455 1854">300 IR</td> </tr> </tbody> </table>	Day 1	Day 2	Day 3 and Following	100 IR	2 x 100 IR	300 IR
Day 1	Day 2	Day 3 and Following					
100 IR	2 x 100 IR	300 IR					

	<p>IR, index of reactivity, a potency unit defined by the formation of a 7-mm wheal in 30 sensitized individuals during product development.(1)</p> <p><u>Pharmacotherapy of Pollen-Induced Allergic Rhinitis</u></p> <p>Several clinical practice guidelines describe pharmacologic treatments of pollen-induced allergic rhinitis/rhinoconjunctivitis.(4-8) There is general agreement that:</p> <ol style="list-style-type: none"> 1. Treatment should be individualized based on symptom severity and duration, comorbidities, and patient age, preference (eg, route of administration, tolerance for adverse effects), and previous treatment history. 2. Measures to increase treatment adherence (eg, shared decision making, consideration of the patient’s school or work schedule, use of a medication calendar or check-off list) are encouraged. 3. Goals of treatment are symptom reduction and improvements in functional capacity and quality of life. 4. A “step-up” (if treatment is inadequate)/“step-down” (if symptom relief is achieved with other interventions, eg, avoidance) approach to treatment is recommended. 5. Allergen avoidance is the first step of treatment but may be unrealistic for some patients. 6. Six medication classes are used to treat allergic rhinitis: H1-antihistamines (oral and intranasal), corticosteroids (oral [short-course for severe disease] and intranasal), leukotriene receptor antagonists (oral), sympathomimetic decongestants (oral and intranasal), chromones (intranasal), and the anticholinergic, ipratropium bromide (intranasal). 7. Treatment should be symptom-specific, eg, oral antihistamines may be less effective for prominent congestion than other treatments; prominent rhinorrhea may respond to intranasal ipratropium; rhinitis-only symptoms may be treated with local (intranasal) rather than systemic (oral) therapy. 8. For mild or intermittent symptoms, oral or nasal antihistamine may be considered first-line treatment. 9. Newer generation (selective) oral antihistamines generally are recommended over older (nonselective) antihistamines. Patients with insomnia and pregnant women may prefer older antihistamines because of their sedating effects and longer safety history, respectively. 10. Intranasal corticosteroids may be effective for more severe or persistent symptoms. 11. Combination treatment (eg, oral antihistamine plus intranasal corticosteroid, intranasal antihistamine and corticosteroid, antihistamine [oral or intranasal] plus sympathomimetic [oral or short-course (≤5 days to avoid rebound congestion) intranasal]) may be effective for symptoms nonresponsive to single medications. 12. Oral sympathomimetics may cause insomnia; their use is limited in patients with certain comorbidities (eg, diabetes mellitus, unstable hypertension). 13. Oral leukotriene receptor antagonists may reduce asthma exacerbations in patients with comorbid asthma.
	<p>Rationale section updated</p>
	<p>In Coding section:</p> <ul style="list-style-type: none"> ▪ Added ICD-9 Code: 477.0 ▪ Added ICD-10 Code: J30.1 ▪ Removed "Experimental / Investigational on all diagnoses related to this medical policy."
	<p>References updated</p>
<p>11-01-2014</p>	<p>Policy posted 10-02-2014 and effective 11-01-2014, 30 days after posting.</p>
	<p>Adopted PTI policy.</p>
	<p>Policy title changed to: "Oral Immunotherapy Agents (Grastek®, Oralair®, Ragwitek™)" from "Sublingual Immunotherapy as a Technique of Allergen-Specific Therapy"</p>
	<p>Description section revised</p>

	<p>▪ Added FDA Indications</p> <p>In Policy section</p> <p>▪ The policy was revised to the current policy language from:</p> <p>"A. Sublingual immunotherapy using Oralair®, Grastek®, or Ragwitek® may be considered medically necessary, when used according to FDA-labelling, for the treatment of pollen-induced allergic rhinitis when the following conditions are met:</p> <ol style="list-style-type: none"> 1. Patient has a history of rhinitis or rhinoconjunctivitis symptoms related to grass or short ragweed pollen exposure. 2. Patient has a documented positive pollen-specific skin test or pollen-specific immunoglobulin E (IgE) test (see Policy Guidelines section). 3. Patient’s symptoms are not adequately controlled by appropriate pharmacotherapy (see Policy Guidelines section). <p>B. Sublingual immunotherapy as a technique of allergy immunotherapy is considered experimental / investigational for all other uses.</p> <p><u>Policy Guidelines</u></p> <p>For Oralair®, Grastek®, or Ragwitek®(1-3):</p> <p>Documentation of Allergy</p> <p>Allergy must be confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies to the species contained in the product or, for Grastek®, Timothy grass pollen extract, to cross-reactive species.</p> <p>Contraindications</p> <p>Contraindications include severe, unstable or uncontrolled asthma; history of any severe local reaction, or any severe systemic allergic reaction to SLIT; and for Grastek® and Ragwitek®, history of eosinophilic esophagitis.</p> <p>Administration and Dose</p> <ol style="list-style-type: none"> 1. Prescribing information includes a black box warning for severe allergic reactions including anaphylaxis. Patients must be prescribed an epinephrine auto-injector and be trained on how to use it. 2. Treatment should begin 12 weeks (16 weeks for Oralair®) before the expected onset of the allergy-inducing pollen season. Each product is dosed once daily and continued throughout the pollen season (preseasonal dosing). 3. The first dose is administered under the supervision of a physician experienced in diagnosing and treating severe allergic reactions. Subsequent doses may be taken at home. 4. All 3 agents are dosed once daily. 5. For Oralair®, dose titration is required in patients 10 to 17 years of age. Titration can be completed over 3 days at home (after the first dose) according to the schedule in Table 1. In patients between 18 to 65 years, no dose titration is needed; treatment is initiated at the maintenance dose of 300 IR (index of reactivity). 6. Grastek® and Ragwitek® both are initiated at the maintenance dose (2800 BAU [bioequivalent allergy unit] and 12 Amb a 1 unit, respectively). <p>Table 1. Oralair® Dosing in Patients Age 10-17 Years(1)</p> <table border="1" style="width: 100%; text-align: center;"> <thead> <tr> <th>Day 1</th> <th>Day 2</th> <th>Day 3 and Following</th> </tr> </thead> <tbody> <tr> <td>100 IR</td> <td>2 x 100 IR</td> <td>300 IR</td> </tr> </tbody> </table> <p>IR, index of reactivity, a potency unit defined by the formation of a 7-mm wheal in 30 sensitized individuals during product development.(1)</p> <p>Pharmacotherapy of Pollen-Induced Allergic Rhinitis</p> <p>Several clinical practice guidelines describe pharmacologic treatments of pollen-induced allergic rhinitis/rhinoconjunctivitis.(4-8) There is general agreement that:</p> <ol style="list-style-type: none"> 1. Treatment should be individualized based on symptom severity and duration, comorbidities, and patient age, preference (eg, route of administration, tolerance for adverse effects), and previous treatment history. 	Day 1	Day 2	Day 3 and Following	100 IR	2 x 100 IR	300 IR
Day 1	Day 2	Day 3 and Following					
100 IR	2 x 100 IR	300 IR					

	<ol style="list-style-type: none"> 2. Measures to increase treatment adherence (eg, shared decision making, consideration of the patient’s school or work schedule, use of a medication calendar or check-off list) are encouraged. 3. Goals of treatment are symptom reduction and improvements in functional capacity and quality of life. 4. A “step-up” (if treatment is inadequate)/“step-down” (if symptom relief is achieved with other interventions, eg, avoidance) approach to treatment is recommended. 5. Allergen avoidance is the first step of treatment but may be unrealistic for some patients. 6. Six medication classes are used to treat allergic rhinitis: H1-antihistamines (oral and intranasal), corticosteroids (oral [short-course for severe disease] and intranasal), leukotriene receptor antagonists (oral), sympathomimetic decongestants (oral and intranasal), chromones (intranasal), and the anticholinergic, ipratropium bromide (intranasal). 7. Treatment should be symptom-specific, eg, oral antihistamines may be less effective for prominent congestion than other treatments; prominent rhinorrhea may respond to intranasal ipratropium; rhinitis-only symptoms may be treated with local (intranasal) rather than systemic (oral) therapy. 8. For mild or intermittent symptoms, oral or nasal antihistamine may be considered first-line treatment. 9. Newer generation (selective) oral antihistamines generally are recommended over older (nonselective) antihistamines. Patients with insomnia and pregnant women may prefer older antihistamines because of their sedating effects and longer safety history, respectively. 10. Intranasal corticosteroids may be effective for more severe or persistent symptoms. 11. Combination treatment (eg, oral antihistamine plus intranasal corticosteroid, intranasal antihistamine and corticosteroid, antihistamine [oral or intranasal] plus sympathomimetic [oral or short-course (≤5 days to avoid rebound congestion) intranasal]) may be effective for symptoms nonresponsive to single medications. 12. Oral sympathomimetics may cause insomnia; their use is limited in patients with certain comorbidities (eg, diabetes mellitus, unstable hypertension). 13. Oral leukotriene receptor antagonists may reduce asthma exacerbations in patients with comorbid asthma." <ul style="list-style-type: none"> ▪ Added Contraindications chart ▪ Added Quantity Limits chart <p>Rationale section updated</p> <p>Coding section reviewed with no changes</p> <p>References updated</p>
<p>04-14-2015</p>	<p>In Policy section:</p> <ul style="list-style-type: none"> ▪ In Item 12 a, removed "prescribed dosage", "within", and "(FDA approved labeled dosage)", and added "requested quantity (dose), "less than or equal to", and "quantity", to read, "The requested quantity (dose) is less than or equal to the program quantity limit." ▪ In Item 12 b, added "ALL of the following, <ol style="list-style-type: none"> i. The requested quantity (dose) is above the set limit AND, ii. One of the following, <ol style="list-style-type: none"> 1) BOTH of the following, <ol style="list-style-type: none"> a) The requested quantity (dose) requested is below the FDA labeled dose AND, b) The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the limit OR, 2) BOTH of the following,

	<p>a) The requested quantity (dose) requested is above the FDA labeled dose AND"</p> <ul style="list-style-type: none"> ▪ In Item 12 b i 2 b, removed "The quantity (dose) requested is greater than the maximum dose recommended in FDA approved labeling, and", to read, "The prescriber has submitted documentation in support of therapy with a higher dose for the intended diagnosis which has been reviewed and approved by the Clinical Review pharmacist."
	Updated References section.
10-01-2015	Published 11-10-2015; effective 10-01-2015.
	In Policy section:
	<ul style="list-style-type: none"> ▪ Updated Quantity Limits for Target Drugs table.
04-15-2016	Updated Description section.
	In Policy section:
	<ul style="list-style-type: none"> ▪ In Item A 11, removed "therapy" and added "the requested agent" to read, "The patient does not have any FDA labeled contraindications to the requested agent." ▪ Added Item B, "Sublingual immunotherapy as a technique of allergy immunotherapy is considered experimental / investigational for all other uses." ▪ Updated FDA Labeled Contraindications table. ▪ Updated Quantity Limits for Target Drugs table.
	Updated Rationale section.
	Updated References section.
05-15-2017	Updated Description section:
	<ul style="list-style-type: none"> ▪ Updated FDA Labeled Indications table.
	In Policy section:
	<ul style="list-style-type: none"> ▪ In Item A 4, added "with" to read, "The prescriber has expertise in allergy or immunology or has consulted with an expert in allergy or immunology" ▪ In Item A 8, added ", or has already been started," to read, "The product will be started, or has already been started, 3-4 months before the expected onset of the applicable pollen season" ▪ Added "4. History of eosinophilic esophagitis" to Oralair in the FDA Labeled Contraindications table.
	Updated Rationale section.
	Updated References section.
04-01-2018	Title has been revised from "Oral Immunotherapy Agents (Grastek®, Oralair®, Ragwitek™).
	Updated Description section.
	In Policy section:
	<ul style="list-style-type: none"> ▪ In Item A, added Odactra to read, "Grastek, Odactra, Oralair, or Ragwitek will be approved when ALL of the following are met:" ▪ In Item A 2 a, added "Grastek, Oralair, or Ragwitek) or licensed house dust mite allergen (Odactra)" to read, "Positive skin test to ONE of the pollen extracts included in the requested agent (Grastek, Oralair, or Ragwitek) or licensed house dust mite allergen (Odactra)" ▪ In Item A 2 b, removed "pollen" and added "IgE" to read, "IgE specific antibodies to ONE of the extracts included in the requested agent" ▪ Added new Item 2 b ii, "Odactra: Dermatophagoides farinae or Dermatophagoides pteronyssinus" ▪ Added new Item A 3 b, "Odactra: between the ages of 18 and 65" ▪ In Item A 7, removed "(within the past 90 days)" and added "currently" to read, "The patient is not currently taking a beta blocker" ▪ In Item A 8, added "If the requested agent is Grastek, Oralair, or Ragwitek:" to read, "If the requested agent is Grastek, Oralair, or Ragwitek: The product will be started,

	<p>or has already been started, 3 to 4 months before the expected onset of the applicable pollen season"</p> <ul style="list-style-type: none"> ▪ Updated the FDA Labeled Contraindications table to include Odactra. ▪ Updated Quantity Limits for Target Agents table.
	Updated Rationale section.
	<p>In Coding section:</p> <ul style="list-style-type: none"> ▪ Removed ICD-9 codes.
	Updated References section.

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1. Blue Cross and Blue Shield of Kansas Family Practice Liaison Committee, July 2003; July 2004.
2. Blue Cross and Blue Shield of Kansas Pediatric Liaison Committee, July 2003; July 2004, July 2014; July 2015.
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5. Blue Cross and Blue Shield of Kansas CB: Family Practice Liaison Committee, Pediatric Liaison Committee, Otolaryngology Liaison Committee, October 2014.