Oral Immunotherapy Prior Authorization with Quantity Limit Program Summary

This program applies to FlexRx Closed, FlexRx Open, FocusRx, GenRx Closed, GenRx Open, Health Insurance Marketplace, and KeyRx formularies.

This is a FlexRx Standard and GenRx Standard program.

The BCBS MN Step Therapy Supplement also applies to this program for all Commercial/HIM lines of business.

POLICY REVIEW CYCLE

Effective Date	Date of Origin
03-01-2024	03-01-2016

FDA APPROVED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
Grastek® (Timothy Grass Pollen Allergen Extract) Sublingual tablet	Treatment of persons 5 through 65 years of age with 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		2
Odactra® (House Dust Mite [*Dermatophagoides farinae* and *Dermatophagoides pteronyssinus*] Allergen Extract) Sublingual tablet	Immunotherapy in persons 12 through 65 years of age for the treatment of house dust mite (HDM)-induced allergic rhinitis, with or without conjunctivitis, confirmed by *in vitro* testing for IgE antibodies to *Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* house dust mites, or by positive skin testing to licensed house dust mite allergen extracts		4
Oralair® (Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass Mixed Pollens Alergen Extract)	Treatment of persons 5 through 65 years of age with 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		1

Agent(s)	FDA Indication(s)	Notes	Ref#
Sublingual tablet			
Ragwitek® (Short Ragweed Pollen Allergen Extract) Sublingual tablet	Treatment of patients 5 through 65 years of age with 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		3

See package insert for FDA prescribing information: https://dailymed.nlm.nih.gov/dailymed/index.cfm

CLINICAL RATIONALE

Allergic Rhinoconjunctivitis	Allergic rhinoconjunctivitis (AR) is an allergic disorder of the nose and eyes with symptoms that can be controlled with allergen avoidance measures and pharmacotherapy. Conventional pharmacotherapy for allergic rhinitis include oral or intranasal antihistamines, intranasal corticosteroids, and leukotriene inhibitors.(6,7) Intranasal corticosteroids are considered the most effective conventional pharmacotherapy.(7) However, many patients continue to have ongoing symptoms and an impaired quality of life. Allergen immunotherapy represents the only currently available treatment that targets the underlying pathophysiology, and it may have a disease-modifying effect. Either the subcutaneous (SCIT) or sublingual (SLIT) routes may be used.(6,7) Per guidelines, allergen immunotherapy should be considered for patients with evidence of IgE sensitization (i.e., positive skin prick test and/or serum-specific IgE) to one or more clinically relevant allergens, who continue to experience symptoms despite conventional pharmacotherapy and allergen avoidance measures.(5-7) Patients receiving SLIT therapy should have regularly scheduled care with a healthcare professional skilled in the assessment and management of patients with allergic conditions.(8)
Safety	All four oral immunotherapy agents carry the same boxed warning:(1,2,3,4) • 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:(1,2,3,4) • 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.(1,2,3,4)

REFERENCES

Number	Reference
1	Oralair prescribing information. Stallergenes SAS. January 2021.
2	Grastek prescribing information. ALK-Abelló, Inc. December 2019.
3	Ragwitek prescribing information. ALK-Abelló, Inc. April 2021.
4	Odactra prescribing information. ALK-Abelló, Inc. January 2023.
5	Global Initiative for Asthma (GINA) 2023 guidelines. Global Strategy for Asthma Management and Prevention. Available at: https://ginasthma.org/gina-reports/.
6	EAACI Guidelines on Allergen Immunotherapy: Allergic Rhinoconjunctivitis. Allergy. 2018;73:765-798.
7	2019 ARIA Care Pathways for Allergen Immunotherapy. Allergy. 2019;74(11):2087-2102.
8	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.

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Odactra	*dust mite mixed ext sl tab	12 SQ-HDM	M ; N ; O ; Y	N		
Oralair children/adolesce	*Grass Mixed Pollen Ext SL Tab 100 IR (Index of Reactivity)*	100 IR	M ; N ; O ; Y	N		
Oralair ; Oralair adult starter pac	*Grass Mixed Pollen Ext SL Tab 300 IR (Index of Reactivity)*	300 IR	M ; N ; O ; Y	N		
Ragwitek	short ragweed pollen allergen extract sl tab	12 AMB A 1-U	M ; N ; O ; Y	N		
Grastek	timothy grass pollen allergen ext sl tab	2800 BAU	M ; N ; O ; Y	N		

POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Grastek	timothy grass pollen allergen ext sl tab	2800 BAU	30	Tablets	30	DAYS			
Odactra	*dust mite mixed ext sl tab	12 SQ-HDM	30	Tablets	30	DAYS			
Oralair ; Oralair adult starter pac	*Grass Mixed Pollen Ext SL Tab 300 IR (Index of Reactivity)*	300 IR	30	Tablets	30	DAYS			

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Oralair children/adolesce	*Grass Mixed Pollen Ext SL Tab 100 IR (Index of Reactivity)*	100 IR	1	Pack	180	DAYS			
Ragwitek	short ragweed pollen allergen extract sl tab	12 AMB A 1-U	30	Tablets	30	DAYS			

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Grastek	timothy grass pollen allergen ext sl tab	2800 BAU	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Odactra	*dust mite mixed ext sl tab	12 SQ-HDM	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Oralair ; Oralair adult starter pac	*Grass Mixed Pollen Ext SL Tab 300 IR (Index of Reactivity)*	300 IR	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Oralair children/adolesce	*Grass Mixed Pollen Ext SL Tab 100 IR (Index of Reactivity)*	100 IR	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Ragwitek	short ragweed pollen allergen extract sl tab	12 AMB A 1-U	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Grastek	timothy grass pollen allergen ext sl tab	2800 BAU	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Odactra	*dust mite mixed ext sl tab	12 SQ-HDM	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Oralair ; Oralair adult starter pac	*Grass Mixed Pollen Ext SL Tab 300 IR (Index of Reactivity)*	300 IR	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Oralair children/adolesce	*Grass Mixed Pollen Ext SL Tab 100 IR (Index of Reactivity)*	100 IR	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ;

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Health Insurance Marketplace/BasicRx ; KeyRx
Ragwitek	short ragweed pollen allergen extract sl tab	12 AMB A 1-U	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Target Agent(s) 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 extracts (Odactra) **OR** B. IgE specific antibodies to ONE of the extracts included in the requested agent: 1. Grastek: Timothy grass or cross-reactive grass 2. Odactra: *Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* 3. Oralair: Sweet vernal, orchard, perennial rye, Timothy, or Kentucky blue grass 4. Ragwitek: Short Ragweed **AND** 3. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., allergy or immunology) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 5. ONE of the following: A. The patient has tried and had an inadequate response to an intranasal corticosteroid AND one other standard allergy agent (e.g., oral or intranasal antihistamines, oral or intranasal corticosteroids, leukotriene inhibitors; note:two separate intranasal corticosteroids meet this criteria) **OR** B. The patient has an intolerance or hypersensitivity to therapy with an intranasal corticosteroid AND one other standard allergy agent **OR** C. The patient has an FDA labeled contraindication to ALL intranasal corticosteroids AND other standard allergy therapies **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL intranasal corticosteroids AND other standard allergy therapies (e.g., oral or intranasal antihistamines, oral or intranasal corticosteroids, leukotriene inhibitors) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 6. The patient will NOT be using the requested agent in combination with subcutaneous injectable immunotherapy for the requested indication **AND**

Module	Clinical Criteria for Approval
	7. 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** 8. The first dose is given in the clinic/hospital under direct supervision from the provider for a period of at least 30 minutes **AND** 9. The patient has been prescribed epinephrine auto-injector for at home emergency use **AND** 10. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL with PA	**Quantity limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** 3. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** C. The prescriber has provided information in support of therapy with a higher dose for the requested indication **Length of Approval**: 12 months