

Market Applicability														
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

*FHK- Florida Healthy Kids

Oralair

(sweet vernal, orchard, perennial rye, Timothy, and Kentucky blue grass mixed pollens allergen extract)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Oralair (sweet vernal, orchard, perennial rye, Timothy, and Kentucky blue grass mixed pollens allergen extract)	100 IR – 3 tablets per grass pollen season for dose titration for children ages 5 -17 years 300 IR - 1 tablet per day

APPROVAL CRITERIA

Requests for Oralair (sweet vernal, orchard, perennial rye, Timothy, and Kentucky blue grass mixed pollens allergen extract) may be approved if the following are met:

- I. Individual is between the ages of 5 and 65 years old; **AND**
- II. Individual has had a trial and inadequate symptom control or intolerance to one nasal steroid and one non-sedating antihistamine (AAO-HNSF 2015); **AND**
- III. Individual has a confirmed prescription for an auto-injectable epinephrine product; **AND**
- IV. Treatment will be initiated at least 16 weeks before the expected onset of grass pollen season and continued throughout the season; **AND**
- V. Individual has a diagnosis of grass pollen-induced allergic rhinitis; **AND**
- VI. Diagnosis has been confirmed by one of the following:
 - A. Positive skin test; **OR**
 - B. Positive *in vitro* testing for pollen-specific IgE antibodies for at least one of the following five grass pollens contained in Oralair:
 1. Sweet vernal
 2. Orchard
 3. Perennial rye
 4. Timothy

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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5. Kentucky blue grass

Oralair (sweet vernal, orchard, perennial rye, Timothy, and Kentucky blue grass mixed pollens allergen extract) may **not** be approved for the following:

- I. Individual has severe, unstable or uncontrolled asthma; **OR**
- II. Individual has a history of any severe systemic allergic reaction; **OR**
- III. Individual is receiving concomitant therapy with other allergen immunotherapy products; **OR**
- IV. Individual has a history of eosinophilic esophagitis.

Notes:

Oralair (sweet vernal, orchard, perennial rye, Timothy, and Kentucky blue grass mixed pollens allergen extract) has a black box warning for severe allergic reactions. Oralair can cause life-threatening allergic reactions such as anaphylaxis and severe laryngopharyngeal edema. Therapy should not be administered to individuals with severe, unstable or uncontrolled asthma. Individuals should be observed in the office for at least 30 minutes following the initial dose and should be prescribed auto-injectable epinephrine. Therapy may not be suitable for individuals with certain underlying medical conditions that may reduce their ability to survive a serious allergic reaction or for those who may be unresponsive to epinephrine or inhaled bronchodilators, such as those taking beta-blockers.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2018. URL: <http://www.clinicalpharmacology.com>. Updated periodically.

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Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: November 27, 2018.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.
5. Seidman MD, Gurgel RK, Lin SY, et al. Clinical Practice Guideline: Allergic Rhinitis. *Otolaryngol Head Neck Surg.* 2015; 152(1 Suppl); S1-43. doi: 10.1177/0194599814561600.

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