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5.20.006

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| **Section:** | Prescription Drugs | **Effective Date:** | January 1, 2025 |
| **Subsection:** | Biologicals | **Original Policy Date:** | September 11, 2014 |
| **Subject:** | Oralair | **Page:** | 1 of 5 |

***Last Review Date:*** December 13, 2024

# Oralair

## Description

### Oralair (Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass Mixed Pollens Allergen Extract)

**Background**
Oralair is an allergen extract consisting of 5 species of grass, formulated into a daily sublingual tablet used to treat grass pollen-induced hay fever / allergies that can cause sneezing, runny or stuffy nose and watery eyes. Oralair contains a mixture of freeze-dried extracts from the pollens of five grasses, including Kentucky Blue Grass, Orchard, Perennial Rye, Sweet Vernal and Timothy (1).

**Regulatory Status**
FDA-approved indication: Oralair is an allergen extract indicated as immunotherapy for the 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 (1).

Oralair has a boxed warning concerning systemic allergic reactions including anaphylaxis and laryngopharyngeal swelling which may be life threatening. The initial dose of Oralair must be administered in a healthcare setting under the supervision of a physician and they must be monitored for at least 30 minutes to watch for signs and symptoms of life-threatening systemic or local allergic reaction. If the patient tolerates the first dose, subsequent doses may be taken at home. The prescriber should prescribe and an auto-injectable epinephrine to patients receiving Oralair with instruction on how to recognize the signs and symptoms of a severe allergic reaction and in the proper use of emergency auto-injectable epinephrine. Instruct

patients to seek immediate medical care upon use of auto-injectable epinephrine and to stop treatment with Oralair (1).

Oralair is contraindicated in patients with severe, unstable, or uncontrolled asthma (rescue inhaler use greater than 2 days or more per week; significantly impaired activity levels due to troublesome symptoms), a history of any severe systemic allergic reaction or severe local reaction after taking any sublingual allergen immunotherapy (1).

Oralair has a boxed warning that therapy might not be suitable for patients with certain underlying medical conditions that may reduce their ability to survive a serious allergic reaction, or who may be unresponsive to epinephrine or inhaled bronchodilators, such as patients on beta-blockers (1).

Sublingual tablet immunotherapy is associated with eosinophilic esophagitis. Oralair is contraindicated in patients with eosinophilic esophagitis (1).

Concomitant dosing of Oralair with other allergen immunotherapy may increase the likelihood of local or systemic adverse reactions to either subcutaneous or sublingual allergen immunotherapy (1).

The safety and effectiveness of Oralair in patients younger than 5 years of age or older than 65 years of age have not been established (1).

**Related policies**
Grastek, Ragwitek

## Policy

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Oralair may be considered **medically necessary** if the conditions indicated below are met.

Oralair may be considered **investigational** for all other indications.

## Prior-Approval Requirements

**Age** 5 through 65 years of age

**Diagnosis**

Patient must have the following:

1. Pollen-induced allergic rhinitis due to one of the following species of grass:
    a. Sweet vernal *(Anthoxanthum odoratum)*
    b. Orchard *(Dactylis glomerata)*
    c. Perennial rye *(Lolium perenne)*
    d. Timothy Grass *(Phleum pretense)*
    e. Kentucky Blue Grass *(Poa pratensis)*

**AND ALL** of the following:

1. Confirmation with either a positive skin test or in vitro testing for pollen-specific IgE antibodies for one or more of the following grasses:
    a. Sweet vernal *(Anthoxanthum odoratum)*
    b. Orchard *(Dactylis glomerata)*
    c. Perennial rye *(Lolium perenne)*
    d. Timothy Grass *(Phleum pretense)*
    e. Kentucky Blue Grass *(Poa pratensis)*
2. Physician has adequate training and experience in the treatment of allergic diseases.
3. Patient has shown unacceptable response to at least one oral or intranasal steroid and at least one oral antihistamine.
4. Absence of severe, unstable or uncontrolled asthma (rescue inhaler use greater than 2 days or more per week; significantly impaired activity levels due to troublesome symptoms )
5. Absence of eosinophilic esophagitis
6. Auto-injectable epinephrine has been prescribed and the patient instructed in its use
7. Will **NOT** be used with other allergen immunotherapies
8. **NO** history of severe local reaction to sublingual allergen immunotherapy

**Prior – Approval *Renewal* Requirements**

**Age** 5 through 65 years of age

**Diagnosis**

Patient must have the following:

1. Pollen-induced allergic rhinitis due to **ONE** of the following species of grass:
    a. Sweet vernal *(Anthoxanthum odoratum)*
    b. Orchard *(Dactylis glomerata)*
    c. Perennial rye *(Lolium perenne)*
    d. Timothy Grass *(Phleum pretense)*
    e. Kentucky Blue Grass *(Poa pratensis)*

**AND ALL** of the following:

1. Absence of severe, unstable or uncontrolled asthma (rescue inhaler use greater than 2 days or more per week; significantly impaired activity levels due to troublesome symptoms )
2. Absence of eosinophilic esophagitis
3. Will **NOT** be used with other allergen immunotherapies

## Policy Guidelines

### Pre - PA Allowance

None

### Prior - Approval Limits

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|---|---|---|
| **Quantity** | 300mg IR | 90 tablets per 90 days |
| **Duration** | 12 months | |

### Prior – Approval *Renewal* Limits

Same as above

## Rationale

**Summary**

Oralair is an allergen extract used to treat allergic rhinitis (hay fever) with or without conjunctivitis (eye inflammation) 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. The safety and effectiveness of Oralair in patients younger than 5 years of age or older than 65 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Oralair while maintaining optimal therapeutic outcomes.

**References**

1. Oralair [package insert]. Antony, France: Stallergenes S.A., Inc.; November 2018.

## Policy History

| Date | Action |
|---|---|
| September 2014 | New Policy Addition and reference update<br>Addition of no history of severe local reaction to sublingual allergen immunotherapy and clarification of uncontrolled asthma per SME |
| December 2014 | Annual review and reference update. |
| March 2015 | Annual review and reference update |
| September 2016 | Annual editorial review and reference update<br>Policy code changed from 5.08.35 to 5.20.06 |
| December 2017 | Annual editorial review and reference update.<br>Addition of no dual therapy to renewal criteria |
| November 2018 | Annual editorial review. Change in age requirement from 10 to 65 years of age to 5 to 65 years of age |
| December 2019 | Annual review |
| December 2020 | Annual review |
| September 2021 | Annual review |
| September 2022 | Annual review |
| September 2023 | Annual review |
| December 2023 | Annual review |
| September 2024 | Annual review |
| December 2024 | Annual review |

## Keywords

**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 13, 2024 and is effective on January 1, 2025.**