
5.20.006

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

Last Review Date: September 19, 2025

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 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

Section:	Prescription Drugs	Effective Date:	October 1, 2025
Subsection:	Biologicals	Original Policy Date:	September 11, 2014
Subject:	Oralair	Page:	2 of 5

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 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

Section:	Prescription Drugs	Effective Date:	October 1, 2025
Subsection:	Biologicals	Original Policy Date:	September 11, 2014
Subject:	Oralair	Page:	3 of 5

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 pratense*)
 - 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 pratense*)
 - 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 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/caregiver 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:

Section:	Prescription Drugs	Effective Date:	October 1, 2025
Subsection:	Biologicals	Original Policy Date:	September 11, 2014
Subject:	Oralair	Page:	4 of 5

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 pratense*)
 - 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 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

Quantity 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.

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

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 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 Policy code changed from 5.08.35 to 5.20.06
December 2017	Annual editorial review and reference update. 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
August 2025	Revised epinephrine requirement to include the option of instructing a caregiver
September 2025	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 19, 2025 and is effective on October 1, 2025.