

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

Reference Number: CP.PMN.XX

Effective Date: 08/17

Last Review Date: 08/17

Line of Business: Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

### **Description**

Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass Mixed Pollens Allergen Extract (Oralair<sup>®</sup>) is a mixed allergen extract.

### **FDA approved indication**

Oralair is 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. Oralair is approved for use in persons 10 through 65 years of age.

Oralair is not indicated for the immediate relief of allergy symptoms.

### **Policy/Criteria**

Provider must submit documentation (~~including which may include~~ office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with Centene Corporation<sup>®</sup> that Oralair is **medically necessary** when the following criteria are met:

#### **I. Initial Approval Criteria**

##### **A. Allergic Rhinitis (must meet all):**

1. Diagnosis of grass pollen-induced allergic rhinitis;
2. Confirmation of a positive skin test or in vitro testing for pollen-specific IgE antibodies for any of the following grass species:
  - a. Sweet Vernal;
  - b. Orchard;
  - c. Perennial Rye;
  - d. Timothy;
  - e. Kentucky Blue Grass;
3. Prescribed by or in consultation with an allergist or immunologist;
4. Failure of one intranasal corticosteroid, unless all are contraindicated or clinically significant adverse effects are experienced;
5. Failure of one oral antihistamine agent at up to maximally indicated doses unless all are contraindicated or clinically significant adverse effects are experienced;
6. Dose does not exceed 1 tablet daily.

**Approval duration: 6 months**

**CLINICAL POLICY**

**Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass Mixed Pollens Allergen Extract**

**B. Other diagnoses/indications**

1. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

**II. Continued Therapy**

**A. Allergic Rhinitis (must meet all):**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Documentation of positive response to therapy [e.g., improvement in nasal symptoms (e.g., congestion, itching, and rhinorrhea), reduction in medication use];
3. If request is for a dose increase, new dose does not exceed 1 tablet daily.

**Approval duration: Duration of request or 12 months (whichever is less)**

**B. Other diagnoses/indications (must meet 1 or 2):**

1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy.

**Approval duration: Duration of request or 12 months (whichever is less); or**

2. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

**III. Diagnoses/Indications for which coverage is NOT authorized:**

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.PMN.53 or evidence of coverage documents;**

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

FDA: Food and Drug Administration

IR: index of reactivity

**V. Dosage and Administration**

<b>Indication</b>	<b>Dosing Regimen</b>	<b>Maximum Dose</b>
Grass pollen-induced allergic rhinitis	Age (years): 10-17: 100 IR (index of reactivity) sublingually (SL) on day 1 followed by 200 IR SL on day 2 and 300 IR SL once daily on day 3 and thereafter.  18-65: 300 IR (index of reactivity) SL once daily	300 IR/day SL

**CLINICAL POLICY**

**Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass Mixed Pollens Allergen Extract**

	Treatment should be initiated 4 months before the expected onset of each grass pollen season and continue treatment throughout the season	
--	---	--

**VI. Product Availability**

Tablets: 100 IR and 300 IR

**VII. Workflow Document**

N/A

**VIII. References**

1. Oralair Prescribing Information. Antony, France: Stallergenes; October 2014. Available at: <http://www.oralair.com/>. Accessed April 5, 2017.
2. Seidman MD, Gurgel RK, Lin SY, et al. Clinical practice guideline: Allergic rhinitis. *Otolaryngol Head Neck Surg.* 2015 Feb;152(1 Suppl):S1-43. doi: 10.1177/0194599814561600.
3. Wallace DV, Dykewicz MS, Bernstein DI, Blessing-Moore J, Cox L, Khan DA, Lang DM, Nicklas RA, Oppenheimer J, Portnoy JM, Randolph CC, Schuller D, Spector SL, Tilles SA, Joint Task Force on Practice, American Academy of Allergy, Asthma&Immunology, American College of Allergy, Asthma and Immunology, Joint Council of Allergy, Asthma and Immunology. The diagnosis and management of rhinitis: an updated practice parameter. *J Allergy Clin Immunol.* 2008;122(2 Suppl):S1-84.
4. Cox L, Nelson H, Lockey R, et al. Allergen immunotherapy: a practice parameter third update. *J Allergy Clin Immunol.* 2011 Jan;127(1 Suppl):S1-55.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	04/17	08/17

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice

## CLINICAL POLICY

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

current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

**Note: For Medicaid members,** when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

©2017 Centene Corporation. All rights reserved. All materials are exclusively owned by Centene Corporation and are protected by United States copyright law and international copyright law. No part of this publication may be reproduced, copied, modified, distributed, displayed, stored in a

## **CLINICAL POLICY**

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

retrieval system, transmitted in any form or by any means, or otherwise published without the prior written permission of Centene Corporation. You may not alter or remove any trademark, copyright or other notice contained herein. Centene® and Centene Corporation® are registered trademarks exclusively owned by Centene Corporation.