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

Reference Number: CP.PMN.85
Effective Date: 11.16.16
Last Review Date: 08.23
Line of Business: Commercial, HIM, 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®) is a mixed allergen extract.

FDA Approved Indication(s)

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 5 through 65 years of age.

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

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® 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. Prescribed by or in consultation with an allergist or immunologist;
3. Age ≥ 5 years and ≤ 65 years;
4. 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;
5. Failure of one intranasal corticosteroid, unless clinically significant adverse effects are experienced or all are contraindicated;
6. Failure of one oral antihistamine at up to maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated;

7. Dose does not exceed (a or b):
   a. Age 5 to 17 years (i, ii, and iii):
      i. Day 1: 100 IR (1 tablet);
      ii. Day 2: 200 IR (2 tablets);
      iii. Day 3 and thereafter (1 and 2):
         1) 300 IR (1 tablet) per day;
         2) 1 tablet per day;
   b. Age ≥ 18 years (i and ii):
      i. 300 IR per day;
      ii. 1 tablet per day.

Approval duration:
Medicaid/HIM – 12 months
Commercial – 12 months or duration of request, whichever is less

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Allergic Rhinitis (must meet all)**:**
1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B)*;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed (a and b):
   a. 300 IR per day;
   b. 1 tablet per day.

Approval duration:

Medicaid/HIM – 12 months
Commercial – 12 months or duration of request, whichever is less

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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 policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
IR: index of reactivity

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
OTC loratadine (Claritin®)	Age 2 to 5 years: 5 mg PO QD Age ≥ 6 years: 10 mg PO QD	10 mg/day
OTC loratadine-D (Claritin-D® 12 and 24 hour)	Age ≥ 12 years: 1 tablet PO BID (12 hr) QD (24 hr)	10 mg/day
OTC cetirizine (Zyrtec®)	6 months to < 1 year: 2.5 mg PO QD Age 1 to 5 years: 2.5-5 mg PO QD	10 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	Age ≥ 6 years: 10 mg PO QD	
OTC fexofenadine (Allegra Allergy®)	Age 6-months to 2 years: 15 mg PO BID Age 2 to 11 years: 30 mg PO BID Age ≥ 12 years: 60 mg PO BID or 180 mg PO QD	180 mg/day
fluticasone propionate (Flonase®)	Age ≥ 4 years: 1-2 sprays each nostril QD Age ≥ 12 years: 1-2 sprays each nostril QD	2 sprays each nostril/day
triamcinolone acetonide (Nasacort AQ®)	Age 2 to 11 years: 1 spray each nostril QD Age ≥ 12 years: 1-2 sprays each nostril QD	Age 2 to 11 years: 1 spray each nostril/day Age ≥ 12 years: 2 sprays each nostril/day
mometasone furoate monohydrate (Nasonex®)	Age 2 to 11 years: 1 spray each nostril QD Age ≥ 12 years: 2 sprays each nostril QD	Age 2 to 11 years: 1 spray each nostril/day Age ≥ 12 years: 2 sprays each nostril/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): severe, unstable or uncontrolled asthma; history of eosinophilic esophagitis; history of any severe systemic allergic reaction or any severe local reaction to sublingual allergen immunotherapy; hypersensitivity to any of the inactive ingredients contained in this product.
- Boxed warning(s): severe allergic reactions

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Grass pollen-induced allergic rhinitis	Age 5 to 17 years: 100 IR (index of reactivity) sublingually (SL) on day 1 followed by 200 IR SL on day 2 and 300 IR SL QD on day 3 and thereafter. Age 18 to 65 years: 300 IR SL QD Treatment should be initiated 4 months before the expected onset of each grass pollen season and continue treatment throughout the season	300 IR/day

VI. Product Availability

Tablets: 100 IR, 300 IR

VII. References

1. Oralair Prescribing Information. Antony, France: Stallergenes; November 2018. Available at: https://oralair.com/assets/pdf/ORALAIR-Prescribing-Information_Medication-Guide-2018.pdf. Accessed April 14, 2023.
2. Wallace DV, Dykewicz MS, Oppenheimer J, et al. Pharmacologic treatment of seasonal allergic rhinitis: synopsis of guidance from the 2017 Joint Task Force on Practice Parameters. Ann Intern Med. 2017 Dec 19;167(12):876-881. Doi: 10.7326/M17-2203.
3. 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.
4. 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.
5. 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.
6. Brozek, JL, Bousquet J, Agache I, et al. Allergic rhinitis and its impact on asthma (ARIA) guidelines-2016 revision. J Allergy Clin Immunol. 2017 Oct;140(4):950-958. Doi: 10.1016/j.jaci.2017.03.050.
7. 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.
8. Dykewicz MS, Wallace DV, Amrol DJ, et al. Rhinitis 2020: A practice parameter update. J Allergy Clin Immunol. 2020; 136(4): 721-767.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
3Q 2019 annual review: no significant changes; corrected age restriction from < 65 years to ≤ 65 years per PI; references reviewed and updated.	04.22.19	08.19
3Q 2020 annual review: no significant changes; references reviewed and updated.	04.06.20	08.20
3Q 2021 annual review: no significant changes; clarified quantity limit for pediatric dose titration; added HIM line of business; references reviewed and updated.	03.22.21	08.21
Revised approval duration for Commercial line of business from length of benefit to 12 months or duration of request, whichever is less	09.28.21	02.22
3Q 2022 annual review: no significant changes; references reviewed and updated.	03.24.22	08.22

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Template changes applied to other diagnoses/indications and continued therapy section.	10.10.22	
3Q 2023 annual review: no significant changes; updated Allegra dosing in Appendix B; references reviewed and updated.	04.14.23	08.23

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 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.