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

Reference Number: ERX.NPA.73
Effective Date: 09.01.18
Last Review Date: 08.21
Line of Business: Commercial, 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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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. Age 5 to 17 years: 100 IR (1 tablet) on Day 1, 200 IR (2 tablets) on Day 2, then 300 IR (1 tablet) per day thereafter;
   b. Age ≥ 18 years: 300 IR (1 tablet) per day.

Approval duration: 12 months

B. Other diagnoses/indications
1. Refer to ERX.PA.01 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 a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 300 IR (1 tablet per day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to ERX.PA.01 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 – ERX.PA.01 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 and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
cetirizine (Zyrtec®)	Age 2 to 5 years: 2.5-5 mg PO QD Age ≥ 6 years: 10 mg PO QD	10 mg/day
desloratadine (Clarinex®)	2 to 5 years: 1.25 mg PO QD 6 to 11 years: 2.5 mg PO QD ≥ 12 years: 5 mg PO QD	5 mg/day
levocetirizine (Xyzal®)	Age 6 to 11 years: 2.5 mg PO QD Age ≥ 12 years: 5 mg PO QD	5 mg/day
budesonide (Rhinocort® Aqua)	6 to 11 years: 1-2 sprays each nostril QD ≥ 12 years: 1-4 sprays each nostril QD	4 sprays each nostril/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 (index of reactivity) 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://www.oralair.com. Accessed March 22, 2021.
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
Policy created.	05.02.18	08.18
No significant changes: pediatric age requirement expanded down to age 5 years from 10 years old per drug labeling changes; references reviewed and updated.	12.19.18	

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; references reviewed and updated.	03.22.21	08.21

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.