RXADVANCE
2 Park Central Drive
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Clinical Policy Title:	sweet vernal, orchard, perennial rye, timothy, and Kentucky blue grass mixed pollens allergen extract
Policy Number:	RxA.613
Drug(s) Applied:	Oralair®
Original Policy Date:	03/06/2020
Last Review Date:	12/07/2020
Line of Business Policy Applies to:	All lines of business

Background

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

It 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.

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

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
sweet vernal, orchard, perennial rye, timothy, and Kentucky blue grass mixed pollens allergen extract (Oralair®)	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 once daily on day 3 and thereafter. Age 18 to 65 years: 300 IR (index of reactivity) SL once daily. Treatment should be initiated 4 months before the expected onset of each grass pollen season and continue treatment throughout the season.	300 IR/day

Dosage Forms

- Tablets: 100 IR, 300 IR

Clinical Policy

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

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 all are contraindicated or clinically significant adverse effects are experienced;
6. Failure of one oral antihistamine at up to maximally indicated doses, unless all are contraindicated or clinically significant adverse effects are experienced;
7. Dose does not exceed 1 tablet per day.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

II. Continued Therapy Approval

A. Allergic Rhinitis (must meet all):

1. Member is currently receiving the medication that has been authorized by RxAdvance or member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 1 tablet per day.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

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 once daily Age ≥ 6 years: 10 mg PO once daily	10 mg/day
OTC loratadine-D (Claritin-D® 12 and 24 hour)	Age ≥ 12 years: 1 tablet PO BID (12 hr) once daily (24 hr)	10 mg/day
OTC cetirizine (Zyrtec®)	Age 2 to 5 years: 2.5-5 mg PO once daily Age ≥ 6 years: 10 mg PO once daily	10 mg/day
OTC fexofenadine (Allegra Allergy®)	Age 6-months to 2 years: 15 mg PO once daily Age 2 to 11 years: 30 mg PO once daily Age ≥ 12 years: 60 mg PO BID or 180 mg PO once daily	180 mg/day
fluticasone propionate (Flonase®)	Age ≥ 4 years: 1-2 sprays each nostril once daily Age ≥ 12 years: 1-2 sprays each nostril once daily	2 sprays each nostril/day
triamcinolone acetonide (Nasacort AQ®)	Age 2 to 11 years: 1 spray each nostril once daily Age ≥ 12 years: 1-2 sprays each nostril once daily	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 once daily Age ≥ 12 years: 2 sprays each nostril once daily	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

APPENDIX D: General Information

- Inform patients of the signs and symptoms of severe allergic reactions and 67 instruct them to seek immediate medical care and discontinue therapy 68 should any of these occur.

- In case of oral inflammation or wounds, stop treatment with Oralair to 70 allow complete healing of the oral cavity.

References

1. Oralair Prescribing Information. Antony, France: Stallergenes; November 2018. Available at: https://www.fda.gov/downloads/BiologicsBloodVaccines/Allergenics/UCM391580.pdf. Accessed September 7, 2020.
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.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1. Background was updated. 2. Dosing information was updated. 3. Commercial approval duration was updated for initial and Continued approval criteria. 4. Continued therapy criteria II.A.1 was rephrased to “Currently receiving medication that has been authorized by Rxadvance..” 5. Appendix D, general information was added. 6. References were reviewed and updated.	09/07/2020	12/07/2020