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 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 daily.
   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 1 tablet daily.
   **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.

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Dose Limit/ Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>cetirizine (Zyrtec®)</td>
<td>Age 2 to 5 years: 2.5-5 mg orally once daily Age ≥ 6 years: 10 mg orally once daily</td>
<td>10 mg/day</td>
</tr>
<tr>
<td>levocetirizine (Xyzal®)</td>
<td>Age 6 to 11 years: 2.5 mg orally once daily Age ≥ 12 years: 5 mg orally once daily</td>
<td>5 mg/day</td>
</tr>
<tr>
<td>fluticasone propionate (Flonase®)</td>
<td>Age ≥ 4 years: 1-2 sprays each nostril daily Age ≥ 12 years: 1-2 sprays each nostril daily</td>
<td>2 sprays each nostril/day</td>
</tr>
<tr>
<td>triamcinolone acetone (Nasacort AQ®)</td>
<td>Age 2 to 11 years: 1 spray each nostril daily Age ≥ 12 years: 1-2 sprays each nostril daily</td>
<td>Age 2 to 11 years: 1 spray each nostril/day Age ≥ 12 years: 2 sprays each nostril/day</td>
</tr>
<tr>
<td>mometasone furoate monohydrate (Nasonex®)</td>
<td>Age 2 to 11 years: 1 spray each nostril daily Age ≥ 12 years: 2 sprays each nostril daily</td>
<td>Age 2 to 11 years: 1 spray each nostril/day Age ≥ 12 years: 2 sprays each nostril/day</td>
</tr>
</tbody>
</table>

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 any severe systemic allergic reaction or any severe local reaction to sublingual allergen immunotherapy
  - A history of eosinophilic esophagitis
Hypersensitivity to any of the inactive ingredients contained in this product

- Boxed warning(s): Oralair can cause life-threatening allergic reactions such as anaphylaxis and severe laryngopharyngeal edema. Do not administer Oralair to patients with severe, unstable or uncontrolled asthma. Oralair may not be suitable for patients:
  - With underlying medical conditions that may reduce their ability to survive a serious allergic reaction
  - Who may be unresponsive to epinephrine or inhaled bronchodilators, such as those taking beta-blockers

V. Dosage and Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grass pollen-induced allergic rhinitis</td>
<td>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.</td>
<td>300 IR/day SL</td>
</tr>
<tr>
<td></td>
<td>Age 18 to 65 years: 300 IR (index of reactivity) SL once daily</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Treatment should be initiated 4 months before the expected onset of each grass pollen season and continue treatment throughout the season</td>
<td></td>
</tr>
</tbody>
</table>

VI. Product Availability

Tablets: 100 IR and 300 IR

VII. References


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.

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