Drug Therapy Guidelines

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

<table>
<thead>
<tr>
<th>Medical Benefit</th>
<th>Applicable</th>
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<tbody>
<tr>
<td>Pharmacy- Formulary 1</td>
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<td>Pharmacy- Formulary 2</td>
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<tr>
<td>Pharmacy- Formulary 3/Exclusive</td>
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<td>Pharmacy- Formulary 4/AON</td>
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**I. Medication Description**

Oralair is a sublingual immunotherapy indicated for grass pollen-induced allergic rhinitis with or without conjunctivitis in patients 5 through 65 years of age, as confirmed by positive skin test or in vitro testing for 5 pollen-specific IgE antibodies (sweet vernal, orchard, perennial rye, Timothy and Kentucky blue grass). Allergen immunotherapy modifies the disease process and is used in patients who are not adequately controlled with environmental or medication changes.

Oralair can cause systemic allergic reactions including anaphylaxis which may be life-threatening. In addition, Oralair can cause severe local reactions, including laryngopharyngeal swelling, which can compromise breathing and be life-threatening. The initial dose of Oralair should be administered in a healthcare setting under the supervision of a physician with experience in the diagnosis and treatment of allergic diseases and prepared to manage a life-threatening systemic or local allergic reaction. Auto-injectable epinephrine should be prescribed to patients receiving Oralair.

**II. Position Statement**

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

**III. Policy**

Coverage of Oralair is provided when the following criteria are met:

- Oralair is prescribed by an Ear, Nose, and Throat specialist with immune therapy training, an Allergist, or an Immunologist **AND**
- Oralair is not used in combination with any other grass pollen immune therapy **AND**
- The ability of the member to adhere to the prescribed regimen is assessed and verified **AND**
- The member is at least 5 years of age and no greater than 65 years of age **AND**
- The member has a history of allergic rhinitis or rhinoconjunctivitis related to grass pollen exposure **AND**
- The member has a positive grass-pollen specific skin test or IgE test **AND**
- The member has tried both of the following treatment modalities without efficacy:
  - Nasal corticosteroid **AND**
  - Nasal or oral antihistamine.
IV. Quantity Limitations

Coverage is available for up to 30 tablets per month for the duration of the season.

V. Coverage Duration

Coverage is available starting four months before the local grass pollen season and can be granted through the end of that season.

VI. Coverage Renewal Criteria

Coverage can be renewed for a new season based upon the original approval criteria.

VII. Billing/Coding Information

Oralair is available as a sublingual tablet equivalent to 100 IR and 300 IR of five grass mixed pollens allergen extract.

VIII. Summary of Policy Changes

- 9/15/14: new policy
- 7/1/15: formulary distinctions made
- 3/15/16: no policy changes
- 1/1/17: no policy changes
- 1/1/18: updated available products
- 1/15/19: updated billing/coding information
- 8/15/19: updated indicated ages
- 1/30/20: no policy changes

IX. References

<table>
<thead>
<tr>
<th>Drug Therapy Guidelines</th>
<th>Oralair® (Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass Mixed Pollens Allergen Extract)</th>
<th>Last Review Date: 12/2019</th>
</tr>
</thead>
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The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary medication will be considered.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.