Clinical Policy: Short Ragweed Pollen Allergen Extract (Ragwitek)
Reference Number: CP.PMN.83
Effective Date: 11.16.16
Last Review Date: 11.17
Line of Business: Commercial, Medicaid

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Short ragweed pollen allergen extract (Ragwitek®) is an allergen extract.

FDA Approved Indication(s)
Ragwitek is indicated as immunotherapy for the treatment of short ragweed pollen-induced allergic rhinitis, with or without conjunctivitis, confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for short ragweed pollen. Ragwitek is approved for use in adults 18 through 65 years of age.

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 Ragwitek is medically necessary when the following criteria are met:

I. Initial Approval Criteria
   A. Allergic Rhinitis (must meet all):
      1. Diagnosis of short ragweed pollen-induced allergic rhinitis;
      2. Prescribed by or in consultation with an allergist or immunologist;
      3. Age ≥ 18 years and < 65 years;
      4. Confirmation of a positive skin test or in vitro testing for pollen-specific IgE antibodies for short ragweed pollen;
      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:
   Medicaid – 12 months
   Commercial – Length of Benefit

   B. Other diagnoses/indications
      1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial and CP.PMN.53 for Medicaid.
CLINICAL POLICY
Short Ragweed Pollen Allergen Extract

II. Continued Therapy
A. Allergic Rhinitis (must meet all):
   1. Currently receiving medication via Centene benefit 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:
   Medicaid – 12 months
   Commercial – Length of Benefit

B. Other diagnoses/indications (must meet 1 or 2):
   1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
      Approval duration: Duration of request or 12 months (whichever is less); or
   2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial 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 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

   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.

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Dose Limit/Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>OTC loratadine (Claritin®)</td>
<td>2 to 5 years: 5 mg PO QD ≥ 6 years: 10 mg PO QD</td>
<td>10 mg/day</td>
</tr>
<tr>
<td></td>
<td>≥ 6 years: 10 mg PO QD</td>
<td></td>
</tr>
<tr>
<td>OTC loratadine-D (Claritin-D® 12 and 24 hour)</td>
<td>≥ 12 years: 1 tablet PO BID (12 hr) QD (24 hr)</td>
<td>10 mg/day</td>
</tr>
<tr>
<td>OTC cetirizine (Zyrtec®)</td>
<td>2 to 5 years: 2.5-5 mg PO QD ≥ 6 years: 10 mg PO QD</td>
<td>10 mg/day</td>
</tr>
<tr>
<td></td>
<td>≥ 6 years: 10 mg PO QD</td>
<td></td>
</tr>
<tr>
<td>OTC fexofenadine (Allegra Allergy®)</td>
<td>6-months to 2 years: 15 mg PO QD 2 to 11 years: 30 mg PO QD ≥ 12 years: 60 mg PO BID or 180 mg PO QD</td>
<td>180 mg/day</td>
</tr>
<tr>
<td>Drug Name</td>
<td>Dosing Regimen</td>
<td>Dose Limit/ Maximum Dose</td>
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<tr>
<td>fluticasone propionate (Flonase®)</td>
<td>≥ 4 years: 1-2 sprays each nostril QD&lt;br&gt; ≥ 12 years: 1-2 sprays each nostril QD</td>
<td>2 sprays each nostril/day</td>
</tr>
<tr>
<td>triamcinolone acetonide (Nasacort AQ®)</td>
<td>2-11 years: 1 spray each nostril QD&lt;br&gt; ≥ 12 years: 1-2 sprays each nostril QD</td>
<td>2-11 years: 1 spray each nostril/day&lt;br&gt; &gt; 12 years: 2 sprays each nostril/day</td>
</tr>
<tr>
<td>Nasonex® (mometasone furoate monohydrate)</td>
<td>2-11 years: 1 spray each nostril QD&lt;br&gt; ≥ 12 years: 2 sprays each nostril QD</td>
<td>2-11 years: 1 spray each nostril/day&lt;br&gt; &gt; 12 years: 2 sprays each nostril/day</td>
</tr>
</tbody>
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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
- Severe, unstable or uncontrolled asthma
- A history of eosinophilic esophagitis

V. Dosage and Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Short ragweed pollen-induced allergic rhinitis</td>
<td>One tablet sublingually daily.</td>
<td>1 tablet per day</td>
</tr>
<tr>
<td>Treatment should be initiated at least 12 weeks before the expected onset of ragweed pollen season and continue treatment throughout the season.</td>
<td></td>
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</tr>
</tbody>
</table>

VI. Product Availability

Tablets: 12 Amb a 1-Unit (Amb a 1-U)

VII. References

<table>
<thead>
<tr>
<th>Reviews, Revisions, and Approvals</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Converted to new template. Minor changes to verbiage and grammar. References updated.</td>
<td>01.12.17</td>
<td>11.17</td>
</tr>
<tr>
<td>3Q 2018 annual review: polices combined for Medicaid and Commercial (CP.CPA.111); added age; Medicaid: increased approval duration to 12 months; Commercial: removed leukotriene modifiers as pdl alternative per 2017 guidelines; references reviewed and updated.</td>
<td>03.28.18</td>
<td>08.18</td>
</tr>
</tbody>
</table>

**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.

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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.

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