Clinical Policy: Timothy Grass Pollen Allergen Extract (Grastek)
Reference Number: CP.PMN.84
Effective Date: 11.16.16
Last Review Date: 08.19
Line of Business: Commercial, HIM, Medicaid

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

Description
Timothy grass pollen allergen extract (Grastek®) is an allergen extract.

FDA Approved Indication(s)
Grastek 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 Timothy grass or cross-reactive grass pollens. Grastek is approved for use in persons 5 through 65 years of age.

Grastek is not indicated for the immediate relief of allergic 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.

It is the policy of health plans affiliated with Centene Corporation® that Grastek 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 Timothy grass pollen or cross-reactive grass pollens (e.g., sweet vernal, orchard, perennial rye, Kentucky blue/June grass, meadow fescue, or redtop);
   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:
Medicaid/HIM – 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, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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 per day.
         Medicaid/HIM – 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, HIM.PHAR.21 for health insurance marketplace, 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, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information
   Appendix A: Abbreviation/Acronym Key
   BAU: bioequivalent allergy unit
   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</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>Drug Name</td>
<td>Dosing Regimen</td>
<td>Dose Limit/ Maximum Dose</td>
</tr>
<tr>
<td>------------------------------</td>
<td>----------------------------------------------------------</td>
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</tr>
<tr>
<td>OTC cetirizine (Zyrtec®)</td>
<td>2 to 5 years: 2.5-5 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</td>
<td>180 mg/day</td>
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<tr>
<td></td>
<td>2 to 11 years: 30 mg PO QD</td>
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<tr>
<td></td>
<td>≥ 12 years: 60 mg PO BID or 180 mg PO QD</td>
<td></td>
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<tr>
<td>fluticasone propionate</td>
<td>≥ 4 years: 1-2 sprays each nostril QD</td>
<td>2 sprays each nostril/day</td>
</tr>
<tr>
<td>(Flonase®)</td>
<td>≥ 12 years: 1-2 sprays each nostril QD</td>
<td></td>
</tr>
<tr>
<td>triamcinolone acetonide</td>
<td>2-11 years: 1 spray each nostril QD</td>
<td>2-11 years: 1 spray each nostril/day</td>
</tr>
<tr>
<td>(Nasacort AQ®)</td>
<td>≥ 12 years: 1-2 sprays each nostril QD</td>
<td></td>
</tr>
<tr>
<td>mometasone furoate monohydrate</td>
<td>2-11 years: 1 spray each nostril QD</td>
<td>2-11 years: 1 spray each nostril/day</td>
</tr>
<tr>
<td>(Nasonex®)</td>
<td>≥ 12 years: 2 sprays each nostril QD</td>
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</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 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 (gelatin, mannitol, and sodium hydroxide) contained in this product
- Boxed warning(s): severe allergic reactions

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>One tablet SL QD</td>
<td>1 tablet/day</td>
</tr>
<tr>
<td></td>
<td>Treatment should be initiated at least 12 weeks before the expected onset of each grass pollen season and continue treatment throughout the season. For sustained effectiveness for one grass pollen season after cessation of treatment, Grastek may be taken daily for three consecutive years.</td>
<td></td>
</tr>
</tbody>
</table>

VI. Product Availability

Tablet: 2,800 bioequivalent allergy units (BAUs)

VII. References


**Reviews, Revisions, and Approvals**

<table>
<thead>
<tr>
<th>Description</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: policies combined for Medicaid and Commercial (CP.CPA.111); age added to policy; increased Medicaid and HIM initial approval duration to 12 months; Commercial: removed leukotriene modifiers as pdl alternative per 2017 guidelines; references reviewed and updated.</td>
<td>04.02.18</td>
<td>08.18</td>
</tr>
<tr>
<td>3Q 2019 annual review: no significant changes; corrected age restriction from &lt; 65 years to ≤ 65 years per PI; references reviewed and updated.</td>
<td>04.22.19</td>
<td>08.19</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.
The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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.

For Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the formulary exception policy.

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