

| Market Applicability |    |          |        |        |    |    |    |    |    |    |    |    |    |    |
|----------------------|----|----------|--------|--------|----|----|----|----|----|----|----|----|----|----|
| Market               | DC | FL & FHK | FL MMA | FL LTC | GA | KS | KY | MD | NJ | NV | NY | TN | TX | WA |
| Applicable           | X  | X        | NA     | NA     | X  | NA | X  | X  | X  | X  | X  | NA | NA | NA |

\*FHK- Florida Healthy Kids

## Grastek (Timothy grass pollen allergen extract)

| Override(s)                           | Approval Duration |
|---------------------------------------|-------------------|
| Prior Authorization<br>Quantity Limit | 1 Year            |

| Medications                                     | Quantity Limit                   |
|---|----------------------------------|
| Grastek (Timothy grass pollen allergen extract) | May be subject to Quantity Limit |

### APPROVAL CRITERIA

Requests for Grastek (Timothy grass pollen allergen extract) may be approved if the following are met:

- I. Individual is between the ages of 5 and 65 years old; **AND**
- II. Individual has had a trial of and inadequate symptom control with one nasal steroid and one non-sedating antihistamine; **AND**
- III. Individual has a confirmed prescription for an auto-injectable epinephrine product; **AND**
- IV. Treatment will be initiated at least 12 weeks before the expected onset of grass pollen season and continued throughout the season; **AND**
- V. Individual has a diagnosis of grass pollen-induced allergic rhinitis; **AND**
- VI. Diagnosis has been confirmed by one of the following:
  - a. Positive skin test; **OR**
  - b. Positive *in vitro* testing for pollen-specific IgE antibodies for Timothy grass or cross-reactive grass pollens.

Grastek (Timothy grass pollen allergen extract) may not be approved for the following:

- I. Individual has severe, unstable or uncontrolled asthma; **OR**
- II. Individual has a history of any severe systemic allergic reaction; **OR**
- III. Individual has a history of eosinophilic esophagitis; **OR**
- IV. Individual is receiving concomitant therapy with other allergen immunotherapy products.

| Market Applicability |    |          |        |        |    |    |    |    |    |    |    |    |    |    |
|----------------------|----|----------|--------|--------|----|----|----|----|----|----|----|----|----|----|
| Market               | DC | FL & FHK | FL MMA | FL LTC | GA | KS | KY | MD | NJ | NV | NY | TN | TX | WA |
| Applicable           | X  | X        | NA     | NA     | X  | NA | X  | X  | X  | X  | X  | NA | NA | NA |

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**Notes:**

Grastek (Timothy grass pollen allergen extract) has a black box warning for severe allergic reactions. Grastek can cause life-threatening allergic reactions such as anaphylaxis and severe laryngopharyngeal restriction. Therapy should not be administered to individuals with severe, unstable or uncontrolled asthma. Individuals should be observed in the office for at least 30 minutes following the initial dose. Therapy may not be suitable for individuals who may be unresponsive to epinephrine or inhaled bronchodilators, such as those taking beta-blockers.

| State Specific Mandates |                |   |
|-------------------------|----------------|---|
| State name              | Date effective | Mandate details (including specific bill if applicable) |
| N/A                     | N/A            | N/A   |

**Key References:**

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2018. URL: <http://www.clinicalpharmacology.com>. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: June 9, 2018.

DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.