## ALLERGEN EXTRACT-TIMOTHY GRASS POLLEN

| Generic | Brand | HICL | GCN | Exception/Other |
|---|---|---|---|---|
| GRASS POLLEN-TIMOTHY, STD | GRASTEK | 22138 | | ROUTE = SUBLINGUAL |

### GUIDELINES FOR USE

### INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of grass pollen-induced allergic rhinitis that is confirmed by a positive skin prick test and/or a positive titre to specific IgE antibodies for Timothy grass or cross-reactive grass pollens?

   If yes, continue to #2.
   If no, do not approve.
   **DENIAL TEXT:** See the initial denial text at the end of the guideline.

2. Was Grastek prescribed or recommended by an allergist, immunologist, or other physician experienced in the diagnosis and treatment of allergic diseases?

   If yes, continue to #3.
   If no, do not approve.
   **DENIAL TEXT:** See the initial denial text at the end of the guideline.

3. Does the patient have persistent and moderate-to-severe symptoms of allergic rhinitis (persistent symptoms are defined as symptoms presenting at least 4 days a week or for at least 4 weeks, and moderate-to-severe symptoms include one or more of the following: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work)?

   If yes, continue to #4.
   If no, do not approve.
   **DENIAL TEXT:** See the initial denial text at the end of the guideline.

4. Does patient have a current claim or prescription for auto-injectable epinephrine within the past 365 days?

   If yes, continue to #5.
   If no, do not approve.
   **DENIAL TEXT:** See the initial denial text at the end of the guideline.

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## ALLERGEN EXTRACT-TIMOTHY GRASS POLLEN

**INITIAL CRITERIA (CONTINUED)**

5. Is the patient at least 5 years of age?

   If yes, **approve for 12 months by HICL for a quantity limit of #1 tablet (2800 BAU) per day.**
   If no, do not approve.
   **DENIAL TEXT:** See the initial denial text at the end of the guideline.

**DENIAL TEXT:** The guideline named **ALLERGEN EXTRACT-TIMOTHY GRASS POLLEN (Grastek)** requires a diagnosis of grass pollen-induced allergic rhinitis and a positive skin prick test and/or a positive titre to specific IgE antibodies for Timothy grass or cross-reactive grass pollens; product must be prescribed or recommended by an allergist, immunologist, or other physician experienced in the diagnosis and treatment of allergic diseases; presentation of persistent and moderate-to-severe symptoms of allergic rhinitis; age of at least 5 years old; and a current claim or prescription for auto-injectable epinephrine.

**RENEWAL CRITERIA**

1. Has the patient experienced an improvement in signs and symptoms of allergic rhinitis from baseline?

   If yes, **approve for 12 months by HICL for a quantity limit of #1 tablet (2800 BAU) per day.**
   If no, do not approve.
   **DENIAL TEXT:** The guideline named **ALLERGEN EXTRACT-TIMOTHY GRASS POLLEN (Grastek)** requires that the patient has experienced an improvement in signs and symptoms of allergic rhinitis from baseline.

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**RATIONALE**
Promote appropriate utilization of Grastek based on FDA approved indication, dosage, and guidelines adopted from ARIA (Allergic Rhinitis and its Impact on Asthma).

Grastek is a grass allergen-specific immunotherapy agent with FDA approval for sublingual use. The approval of oral allergen immunotherapy for allergic rhinitis provides a convenient and safe alternative to customary allergy shots. Grastek improves symptoms of allergic rhino conjunctivitis and reduces use of rescue medication in adults and children. Allergen immunotherapy should be considered in patients who have persistent and moderate to severe symptoms despite pharmacotherapy, patients who experience intolerable side effects to medications, and those desiring to limit cost burden associated with chronic medication use. According to ARIA guidelines, persistent symptoms are defined as symptoms presenting at least 4 days a week or for at least 4 weeks, and moderate to severe symptoms include of one or more of the following items: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work.

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## ALLERGEN EXTRACT-TIMOTHY GRASS POLLEN

### RATIONALE (CONTINUED)

Side effects are considered mild, with the majority of adverse events involving oral pruritus (26.7% Grastek, 3.5% placebo), throat irritation (22.6% Grastek, 2.8% placebo), ear pruritus (12.5% Grastek, 1.1% placebo), and mouth edema (11.1% Grastek, 0.8% placebo). There were no reports of death or anaphylaxis during clinical trials.

Grastek has a black block warning that cites the following: Grastek can cause life-threatening allergic reactions such as anaphylaxis and severe laryngopharyngeal edema; Do not administer Grastek to patients with severe, unstable or uncontrolled asthma; Observe patients in the office for at least 30 minutes following the initial dose; Prescribe auto-injectable epinephrine, instruct and train patients on its appropriate use, and instruct patients to seek immediate medical care upon its use; Grastek may not be suitable for patients with certain underlying medical conditions that may reduce their ability to survive a serious allergic reaction; Grastek may not be suitable for patients who may be unresponsive to epinephrine or inhaled bronchodilators, such as those taking beta-blockers.

### DOSAGE
For children and adults 5 to 65 years of age, the dose is 1 tablet (2800 BAU) daily.

### FDA APPROVED INDICATION
Grastek (Timothy grass pollen extract) approved and indicated 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, in people ages 5 through 65 years.

### REFERENCES

- Brozek JL, Bousquet J, Baena-Cagnani CE, Bonini S, Canonica GW, Casale TB, et al. Allergic Rhinitis and Its Impact on Asthma (ARIA) guidelines: 2010 revision. J Allergy Clin Immunol. 2010;126:466–476.
- Merck Sharp & Dohme Corp. Grastek Package Insert. Whitehouse Station, NJ. April 2014.


| Library | Commercial | NSA |
|---|---|---|
| Yes | Yes | No |

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