

## Commercial/Healthcare Exchange PA Criteria

*Effective: June 2014*

**Prior Authorization:** Grastek

**Products Affected:** Grastek (Timothy grass pollen allergen extract) oral tablet

**Medication Description:** Grastek is an allergen extract 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.

**Covered Uses:** 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.

**Exclusion Criteria:**

1. Immediate relief of allergic symptoms
2. Severe, unstable or uncontrolled asthma
3. Patients with a history of any severe systemic allergic reaction
4. Patients with a history of any severe local reaction after taking any sublingual allergen immunotherapy
5. Patients with a history of eosinophilic esophagitis
6. Hypersensitivity to any of the inactive ingredients contained in Grastek [gelatin, mannitol and sodium hydroxide] contained in this product
7. Concomitant use with subcutaneous immunotherapy (“allergy shots”)

**Required Medical Information:**

1. Diagnosis
2. Previous medications tried/failed

**Age Restrictions:** 5 to 65 years of age

**Prescriber Restrictions:** Prescribed by an allergy specialist (allergist, immunologist, or pulmonologist).

**Coverage Duration:** 12 weeks.

Subsequent approval will be based on current progress notes from the physician documenting efficacy.

**Other Criteria:**

- A. Patients a diagnosis of allergic rhinitis with or without conjunctivitis; AND
- B. Diagnosis has been confirmed by a positive skin test or in vitro testing for pollen-specific IgE antibodies to Timothy grass; AND
- C. Patient has had an inadequate trial, intolerance, or contraindication to at least ONE nasal corticosteroid for allergic rhinitis (e.g. mometasone furoate); AND
- D. Patient has had an inadequate trial, intolerance, or contraindication to at least ONE other oral medication for allergic rhinitis (e.g. desloratadine, levocetirizine, Montelukast, etc.).

**References:**

1. Product Information: GRASTEK(R) sublingual oral tablets, timothy grass pollen allergen extract sublingual oral tablets. Merck & Co, Inc. (per FDA), Whitehouse Station, NJ, 2014.

**Policy Revision history**

<b>Rev #</b>	<b>Type of Change</b>	<b>Summary of Change</b>	<b>Sections Affected</b>	<b>Date</b>
1	New Policy	New Policy	All	06/2014
2	Update	Moved to updated template Revision History: 11/16, 2/17	All	02/03/2020