Grastek
(Timothy grass pollen allergen extract)

Override(s)	Approval Duration
Prior Authorization 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 (AAO-HNSF 2015, AAAAI/ACAAI 2020); **AND**
III. Individual has a prescription for an auto-injectable epinephrine agent; **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 verified 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 any severe local reaction after taking any sublingual allergen immunotherapy; **OR**
IV. Individual has a history of eosinophilic esophagitis; **OR**
V. Individual is receiving concomitant therapy with other allergen immunotherapy agents; **OR**
VI. Individual is using for the immediate relief of allergic symptoms.

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.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Dykewicz MS, Wallace DV, Amrol DJ, et al. Joint Task Force on Practice Parameters (JTFPP), representing the American Academy of Allergy, Asthma & Immunology (AAAAI) and the American College of Allergy, Asthma & Immunology (ACAAI). Rhinitis 2020: A practice parameter update. *J Allergy Clin Immunol.* 2020; 146:721.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
6. Seidman MD, Gurgel RK, Lin SY, et al. Clinical Practice Guideline: Allergic Rhinitis. *Otolaryngol Head Neck Surg.* 2015; 152(1 Suppl); S1-43. doi: 10.1177/0194599814561600.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.