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## Grastek (timothy grass pollen allergen extract)

### NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

### BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

### DESCRIPTION

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

#### FDA-Approved Indications

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.

### POLICY

#### Initial Criteria for Approval

- I. Grastek will be covered with prior authorization when the following criteria are met:
  - Grastek is being prescribed as immunotherapy for the treatment of grass pollen-induced allergic rhinitis  
**AND**
  - The diagnosis has been confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for Timothy grass or cross-reactive grass pollens  
**AND**

- The patient does not have any of the following: A) Severe, unstable or uncontrolled asthma, B) History of any severe systemic allergic reaction or any severe local reaction to sublingual allergen immunotherapy, C) History of eosinophilic esophagitis  
**AND**
- The requested drug is being prescribed by or in consultation with an allergist/immunologist

**Approval will be for 12 months.**

### **Dosing and Administration**

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

## **PROCEDURES AND BILLING CODES**

***To report provider services, use appropriate CPT\* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.***

- Code(s), if applicable

## **REFERENCES**

- Grastek [package insert]. Whitehouse Station, NJ: Merck& Co., Inc.; October 2017.
- AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; [http://online.lexi.com/lco/action/index/dataset/complete\\_ashp](http://online.lexi.com/lco/action/index/dataset/complete_ashp) [available with subscription]. Accessed March 2018.
- Micromedex Solutions [database online]. Greenwood Village, CO: Truven Health Analytics Inc. Updated periodically. [www.micromedexsolutions.com](http://www.micromedexsolutions.com) [available with subscription]. Accessed March 2018.
- Agency for Healthcare Research and Quality. Allergen-Specific Immunotherapy for the Treatment of Allergic Rhinoconjunctivitis and/or Asthma: Comparative Effectiveness Review. U.S. Department of Health and Human Services; 2013. <https://www.effectivehealthcare.ahrq.gov/topics/asthma-immunotherapy-2010/research>. Accessed March 2018.
- Wallace DV, Dykewicz MS. The diagnosis and management of rhinitis: an updated practice parameter. *J Allergy Clin Immunol.* 2008; 122(2): S1-S84.

## **POLICY HISTORY**

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