Grastek

Description
Grastek (timothy grass pollen allergen extract)

Background
Grastek is an allergen extract formulated into a daily sublingual tablet used to treat grass pollen-induced hay fever / allergies that can cause sneezing, runny or stuffy nose and watery eyes. Timothy Grass is one of the most common grasses in the United States and has been demonstrated to be cross-reactive with other grasses, including Sweet Vernal, orchard (also known as cocksfoot), perennial rye, Kentucky Blue (also known as June Grass), meadow fescue and redtop (1).

Regulatory Status
FDA-approved indication: 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 (2).

Grastek has a boxed warning concerning systemic allergic reactions including anaphylaxis and laryngopharyngeal swelling which may be life threatening. The initial dose of Grastek must be administered in a healthcare setting under the supervision of a physician and they must be monitored for at least 30 minutes to watch for signs and symptoms of life-threatening systemic or local allergic reaction. If the patient tolerates the first dose, subsequent doses may be taken at home. The prescriber should prescribe and an auto-injectable epinephrine to patients receiving Grastek with instruction on how to recognize the signs and symptoms of a severe allergic reaction and in the proper use of emergency auto-injectable epinephrine. Instruct
patients to seek immediate medical care upon use of auto-injectable epinephrine and to stop treatment with Grastek (2).

Grastek is contraindicated in patients with severe, unstable or uncontrolled asthma (rescue inhaler use greater than 2 days or more per week; significantly impaired activity levels due to troublesome symptoms (3)), a history of any severe systemic allergic reaction or severe local reaction after taking any sublingual allergen immunotherapy (2).

Sublingual tablet immunotherapy is associated with eosinophilic esophagitis. Grastek is contraindicated in patients with eosinophilic esophagitis (2).

Concomitant dosing of Grastek with other allergen immunotherapy may increase the likelihood of local or systemic adverse reactions to either subcutaneous or sublingual allergen immunotherapy (2).

The safety and effectiveness of Grastek in patients younger than 5 years of age or older than 65 years of age have not been established (2).

**Related policies**
Oralair, Ragwitek

**Policy**

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Grastek may be considered **medically necessary** in patients 5 through 65 years of age for the treatment of grass pollen-induced allergic rhinitis that has been confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for Timothy grass or cross-reactive grass pollens; physician has adequate training and experience in the treatment of allergic diseases; patient has shown unacceptable response to at least one oral or intranasal steroid and at least one oral antihistamine; absence of severe, unstable or uncontrolled asthma (rescue inhaler use greater than 2 days or more per week; significantly impaired activity levels due to troublesome symptoms); absence of eosinophilic esophagitis; auto-injectable epinephrine has been prescribed and the patient instructed in its use; will not be used with other allergen immunotherapies; and no history of severe local reaction to sublingual allergen immunotherapy.

Grastek may be considered **investigational** in patients under 5 years of age or older than 65 years of age or in patients without grass pollen-induced allergic rhinitis.
Prior-Approval Requirements

Age 5 through 65 years of age

Diagnosis Patient must have the following:

Timothy grass (*Phleum pretense*) or cross-reactive grass pollen-induced allergic rhinitis

**AND ALL** of the following:

1. Confirmation with either a positive skin test or in vitro testing for pollen-specific IgE antibodies for Timothy grass or cross reactive grass pollen
2. Physician has adequate training and experience in the treatment of allergic diseases.
3. Patient has shown unacceptable response to at least one oral or intranasal steroid and at least one oral antihistamine.
4. Absence of severe, unstable or uncontrolled asthma (rescue inhaler use greater than 2 days or more per week; significantly impaired activity levels due to troublesome symptoms)
5. Absence of eosinophilic esophagitis
6. Auto-injectable epinephrine has been prescribed and the patient instructed in its use
7. Will **NOT** be used with other allergen immunotherapies
8. **NO** history of severe local reaction to sublingual allergen immunotherapy

Prior – Approval *Renewal* Requirements

Age 5 through 65 years of age

Diagnosis Patient must have the following:

Timothy grass (*Phleum pretense*) or cross reactive grass pollen induced allergic rhinitis

**AND ALL** of the following:

1. Absence of severe, unstable or uncontrolled asthma (rescue inhaler use greater than 2 days a week, significantly impaired activity levels
Policy Guidelines

Pre - PA Allowance
None

Prior - Approval Limits

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<thead>
<tr>
<th>Quantity</th>
<th>90 tablets per 90 days</th>
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<tr>
<td>Duration</td>
<td>12 months</td>
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Prior – Approval Renewal Limits

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Rationale

Summary
Grastek is an allergen extract used to treat 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. The safety and effectiveness of Grastek in patients younger than 5 years of age or older than 65 years of age have not been established (2).

Prior authorization is required to ensure the safe, clinically appropriate and cost effective use of Grastek while maintaining optimal therapeutic outcomes.

References
This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 3, 2015 and is effective January 1, 2016.

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