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5.20.007

Section:	Prescription Drugs	**Effective Date:**	January 1, 2025
Subsection:	Biologicals	**Original Policy Date:**	September 11, 2014
Subject:	Grastek	**Page:**	1 of 5

Last Review Date: December 13, 2024

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 (1).

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 (1).

Grastel has a boxed warning that therapy might not be suitable for patients with certain underlying medical conditions or who may be unresponsive to epinephrine or inhaled bronchodilators, such as patients on beta-blockers (1).

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 (2)), a history of any severe systemic allergic reaction or severe local reaction after taking any sublingual allergen immunotherapy (1).

Sublingual tablet immunotherapy is associated with eosinophilic esophagitis. Grastek is contraindicated in patients with eosinophilic esophagitis (1).

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 (1).

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 (1).

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** if the conditions indicated below are met.

Grastek may be considered **investigational** for all other indications.

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 due to troublesome symptoms)
2. Absence of eosinophilic esophagitis

3. Will **NOT** be used with other allergen immunotherapies

Policy Guidelines

Pre - PA Allowance
None

Prior - Approval Limits

Quantity 90 tablets per 90 days

Duration 12 months

Prior – Approval *Renewal* Limits
Same as above

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 (1).

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

References
1. Grastek [package insert]. Horsholm, Denmark: ALK-Abello Inc.; December 2019.
2. National Heart, Lung, and Blood Institute: Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma 2007.

Policy History

Date	Action
September 2014	New policy addition and reference update Addition of no history of severe local reaction to sublingual allergen immunotherapy and clarification of uncontrolled asthma per SME

December 2014	Annual review and reference update
December 2015	Annual editorial review
September 2016	Annual editorial review and reference update Policy number change from 5.08.36 to 5.20.07
December 2017	Annual editorial review and reference update. Addition of no dual therapy to renewal criteria
November 2018	Annual review
December 2019	Annual review
December 2020	Annual review and reference update
June 2021	Annual review
June 2022	Annual review
June 2023	Annual review. Changed policy number to 5.20.007
December 2023	Annual review
June 2024	Annual review
December 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 13, 2024 and is effective on January 1, 2025.