GRASTEK
(timothy grass pollen allergen extract)

RATIONALE FOR INCLUSION IN PA PROGRAM

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).

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.