BlueCross BlueShield
Federal Employee Program

RAGWITEK
(short ragweed pollen allergen extract)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Ragwitek is a short ragweed pollen extract formulated into a daily sublingual tablet used to treat short ragweed pollen-induced hay fever / allergies that can cause sneezing, runny or stuffy nose and watery eyes (1).

Regulatory Status

FDA-approved indication: Ragwitek is an allergen extract indicated as immunotherapy for the treatment of short ragweed pollen-induced allergic rhinitis, with or without conjunctivitis, confirmed by positive skin test or *in vitro* testing for pollen-specific IgE antibodies for short ragweed pollen. Ragwitek is approved for use in persons 5 through 65 years of age (1).

Ragwitek has a boxed warning concerning severe allergic reactions including anaphylaxis and laryngopharyngeal swelling which may be life threatening. The initial dose of Ragwitek 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. Patients should be prescribed an auto-injectable epinephrine and instructed on its appropriate use. Patients should seek immediate medical care upon use of auto-injectable epinephrine and to stop treatment with Ragwitek. Ragwitek 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).

Ragwitek 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), a history of any severe systemic allergic reaction or severe local reaction after taking any sublingual allergen immunotherapy. Eosinophilic esophagitis has been reported in association with sublingual tablet immunotherapy. Discontinue Ragwitek and consider a diagnosis of eosinophilic esophagitis in patients who experience severe or persistent gastro-esophageal including dysphagia or chest pain. Ragwitek is contraindicated in patients with eosinophilic esophagitis (1).

Ragwitek can cause local reactions in the mouth or throat that could compromise upper airway.

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Consider discontinuation of Ragwitek in patients who experience persistent and escalating adverse reactions (1).

Ragwitek has not been studied in subjects who are receiving concomitant allergen immunotherapy. Concomitant dosing of Ragwitek 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 Ragwitek in patients younger than 5 years of age or older than 65 years of age have not been established (1).

Summary

Ragwitek is an allergen extract used to treat short ragweed pollen-induced allergic rhinitis with or without conjunctivitis confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for short ragweed pollen. The safety and effectiveness of Ragwitek 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 Ragwitek while maintaining optimal therapeutic outcomes.

References

1. Ragwitek [package insert]. Horsholm, Denmark: ALK-Abello Inc.; April 2021.