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5.20.005

Section:	Prescription Drugs	**Effective Date:**	October 1, 2024
Subsection:	Biologicals	**Original Policy Date:**	July 11, 2014
Subject:	Ragwitek	**Page:**	1 of 5

Last Review Date: September 6, 2024

Ragwitek

Description

Ragwitek (short ragweed pollen allergen extract)

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. 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).

Related policies
Grastek, Oralair

Policy

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

Ragwitek may be considered **medically necessary** if the conditions indicated below are met.

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

Prior-Approval Requirements

Age 5 through 65 years of age

Diagnosis

Patient must have the following:

Short ragweed 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 short ragweed 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 following:

Short ragweed pollen-induced allergic rhinitis

AND ALL of the following:

1. 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)
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

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.

Policy History

Date	Action
July 2014	New Policy Addition
September 2014	Annual review and reference update Addition of no history of severe local reaction to sublingual allergen immunotherapy and clarification of uncontrolled asthma per SME Age requirement changed to 18 years to 65 years of age
December 2014	Annual review and reference update
December 2015	Annual editorial review
September 2016	Annual editorial review and reference update

	Policy code changed from 5.08.34 to 5.20.05
December 2017	Annual editorial review and reference update Addition of no dual therapy to renewal criteria
November 2018	Annual review and reference update
December 2019	Annual review
December 2020	Annual review and reference update
May 2021	Changed age requirement from 18 to 65 years of age to 5 to 65 years of age per newest package insert
September 2021	Annual review
September 2022	Annual review
September 2023	Annual review
December 2023	Annual review
September 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 6, 2024 and is effective on October 1, 2024.