PRIOR AUTHORIZATION POLICY

POLICY: Allergen Immunotherapy – Ragwitek Prior Authorization Policy
- Ragwitek® (short ragweed pollen allergen extract sublingual tablets – ALK-Abello)

REVIEW DATE: 08/05/2020

OVERVIEW

Ragwitek is a ragweed pollen allergen extract sublingual tablet indicated as immunotherapy for the treatment of patients 18 to 65 years of age with short ragweed pollen-induced allergic rhinitis with or without conjunctivitis confirmed by a positive skin test or *in vitro* test for pollen-specific immunoglobulin E (IgE) antibodies for short ragweed pollen.[1] Ragwitek is not indicated for the immediate relief of allergy symptoms. Ragwitek is dosed once daily and must be initiated at least 12 weeks before the expected onset of ragweed pollen season and continued throughout the season.

Clinical Efficacy

Clinical trials enrolled adults with allergic rhinitis with or without conjunctivitis to have their diagnosis confirmed by a positive skin prick test and positive *in vitro* testing for serum IgE antibodies for short ragweed. In these patients, therapy with Ragwitek prior to and during the ragweed pollen season resulted in a 24% to 27% improvement in patients' Total Combined Score (a measurement of both allergic rhinitis with or without conjunctivitis symptoms and relief medication use) compared with placebo.[2,3] Ragwitek has also been evaluated in pediatric patients 5 to 17 years of age with allergic rhinitis with or without conjunctivitis; however, it is not indicated in this patient population.[1,8]

Guidelines

Numerous guidelines address allergic rhinitis and allergen immunotherapy. In general, allergen immunotherapy should be considered for patients with allergic rhinitis or allergic asthma and an inadequate response to medical therapy who have evidence of specific IgE antibodies to clinically relevant allergens.[4-7] FDA-approved sublingual immunotherapy agents, including Ragwitek, are recommended to be used only for the treatment of allergic rhinitis with or without conjunctivitis and not for other off-label conditions.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Ragwitek. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Ragwitek is recommended in those who meet the following criteria:

FDA-Approved Indications

1. **Short Ragweed Pollen-Induced Allergic Rhinitis.** Approve for 1 year if the patient meets ALL of the following criteria (A, B and C):
   - **A)** Patient is ≥ 18 years of age;[1] AND
   - **B)** Ragwitek therapy is initiated 12 weeks prior to the expected onset of the short ragweed pollen season; AND
   - **C)** The diagnosis of short ragweed pollen-induced allergic rhinitis is confirmed by meeting ONE of the following conditions (i or ii):
     - **i.** Patient has a positive skin test response to short ragweed pollen; OR
     - **ii.** Patient has a positive *in vitro* test (i.e., a blood test) for allergen-specific immunoglobulin E (IgE) antibodies for short ragweed pollen.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Ragwitek is not recommended in the following situations:

1. **Concurrent Use of Ragwitek with Subcutaneous Allergen Immunotherapy (e.g., allergy shots) or Sublingual Allergen Immunotherapy (e.g., Grastek® [Timothy grass pollen allergen extract sublingual tablets], Oralair® [Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass mixed pollens allergen extract sublingual tablets], Odactra™ [house dust mite {*Dermatophagoides farina* and *Dermatophagoides pteronyssinus*} allergen extract sublingual tablets]).** The efficacy of Ragwitek has not been evaluated in patients who are receiving concomitant allergen immunotherapy.[1] Approved product labeling for Ragwitek states that concomitant dosing with other allergen immunotherapy may increase the risk of local or systemic adverse events to either subcutaneous or sublingual allergen immunotherapy. A Joint Practice Parameter specifically addressing sublingual immunotherapy (2017) highlights that no studies have evaluated the efficacy of multiple sublingual immunotherapy tablets administered together.[8] There is a need for further investigation to determine efficacy and optimal formulations for multi-allergen sublingual immunotherapy.

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

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4. Cox L, Nelson H, Lockey R, et al. Allergen immunotherapy: a practice parameter third update. *J Allergy Clin Immunol.* 2011;127(1):S1-S53.
5. Canonica GW, Cox L, Pawankar R, et al. Sub-lingual Immunotherapy World Allergy Organization Position Paper 2013 Update. *WAO Journal.* 2014;7(6):1-52.
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7. Greenhawt M, Oppenheimer J, Nelson M, et al. Sublingual immunotherapy: a focused allergen immunotherapy practice parameter update. *Ann Allergy Asthma Immunol.* 2017;118:276-282.
8. Nolte H, Bernstein D, Nelson HS, et al. Efficacy and safety of ragweed SLIT-tablet in children with allergic rhinoconjunctivitis in a randomized, placebo-controlled trial. *J Allergy Clin Immunol Pract.* 2020;8(7):2322-2331.