PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 08/31/2022

OVERVIEW

Ragwitek, a ragweed pollen allergen extract, is indicated as immunotherapy for the treatment of patients 5 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 of Ragwitek enrolled adults and pediatric with allergic rhinitis with or without conjunctivitis. Patients had their diagnosis confirmed by a positive skin prick test and positive *in vitro* testing for serum IgE antibodies for short ragweed.[1-4]

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 Indication

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 ≥ 5 years of age; 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 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 or Sublingual Allergen Immunotherapy.** Note: This includes allergy shots as well as 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.

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

1. Ragwitek® sublingual tablets [prescribing information]. Horsholm, Denmark: ALK-Abello; April 2021.
2. Nolte H, Hebert J, Berman G, et al. Randomized controlled trial of ragweed allergy immunotherapy tablet efficacy and safety in North American adults. *Ann Allergy Asthma Immunol.* 2013:110;450-456.
3. Creticos PS, Maloney J, Bernstein DI, et al. Randomized controlled trial of a ragweed allergy immunotherapy tablet in North American and European adults. *J Allergy Clin Immunol.* 2013:131(5);1342-1349.
4. 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.