PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 11/12/2025

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

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 patients with allergic rhinitis with or without conjunctivitis.[1-4] Patients had their diagnosis confirmed by a positive skin prick test and positive *in vitro* testing for serum IgE antibodies for short ragweed.

POLICY STATEMENT

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

Ragwitek® (short ragweed pollen allergen extract sublingual tablets – ALK-Abello) is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

1. **Short Ragweed Pollen-Induced Allergic Rhinitis.** Approve for 1 year if the patient meets ALL of the following (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 (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 COVERED

Ragwitek® (short ragweed pollen allergen extract sublingual tablets – ALK-Abello) is(are) considered not medically necessary for ANY other use(s) including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

1. **Concurrent Use of Ragwitek with Other Allergen Immunotherapy.** Note: This includes subcutaneous allergen immunotherapy (i.e., "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), and Palforzia® (peanut [*Arachis hypogaea*] allergen powder-dnfp for oral administration). 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.

REFERENCES

1. Ragwitek® sublingual tablets [prescribing information]. Horsholm, Denmark: ALK-Abello; September 2022.
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.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	09/13/2023
Annual Revision	No criteria changes.	10/09/2024
Annual Revision	**Conditions Not Covered, Concurrent Use of Ragwitek with Subcutaneous Allergen Immunotherapy or Sublingual Allergen Immunotherapy:** Palforzia (peanut [*Arachis hypogaea*] allergen powder-dnfp for oral administration) was added as an example of sublingual allergen immunotherapy.	10/08/2025
Early Annual Revision	**Conditions Not Covered, Concurrent Use of Ragwitek with Other Allergen Immunotherapy:** This Condition Not Recommended for Approval was updated from "Concurrent Use of Ragwitek with Subcutaneous Allergen Immunotherapy or Sublingual Allergen Immunotherapy" to as stated. The "Note" was updated to clarify that "allergy shots" are subcutaneous allergen immunotherapy.	11/12/2025