Effective Date **1/1/2025**
Coverage Policy Number **IP0518**

Ragwitek

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Related Coverage Resources

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 and have discretion in making individual coverage determinations. 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.

Overview

This policy supports medical necessity review for generic name Ragwitek® (short ragweed pollen allergen extract sublingual tablets).

Medical Necessity Criteria

Ragwitek (short ragweed pollen allergen extract sublingual tablets) is considered medically necessary when the following are met:

Short Ragweed Pollen-Induced Allergic Rhinitis. Individual meets ALL of the following criteria:

A. Age 5 years old or older
B. Diagnosis confirmed by **ONE** of the following:
    a. Positive skin test response to short ragweed pollen

b. Positive *in vitro* test (i.e., a blood test) for allergen-specific immunoglobulin E (IgE) antibodies for short ragweed pollen

C. Documentation of failure, contraindication, or intolerance to **BOTH** of the following:
   a. Intranasal corticosteroid therapy
   b. Either oral or intranasal antihistamine

D. Treatment will be initiated at least 12 weeks before the onset of ragweed pollen season.

When criteria are met, a maximum of 1 tablet per day will be covered.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Reauthorization Criteria

Continuation of Ragwitek (short ragweed pollen allergen extract sublingual tablets) is considered medically necessary for short ragweed pollen-induced allergic rhinitis when the above medical necessity criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration: up to 12 months
Reauthorization approval duration: up to 12 months

Conditions Not Covered

Any other use is considered experimental, investigational or unproven, including the following (this list may not be all inclusive):

1. **Concurrent Use of Ragwitek with Subcutaneous Allergen Immunotherapy or Sublingual Allergen Immunotherapy.**
   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.

Background

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. 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]

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.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	No criteria changes	1/1/2025

The policy effective date is in force until updated or retired.