ALLERGEN EXTRACT-SHORT RAGWEED POLLEN

Generic	Brand	HICL	GCN	Exception/Other
WEED POLLEN-SHORT RAGWEED	RAGWITEK	41079		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of ragweed pollen-induced allergic rhinitis that is confirmed by a positive skin prick test or in vitro testing for pollen-specific IgE antibodies for short ragweed pollen?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Was Ragwitek prescribed or recommended by an allergist, immunologist, or other physician experienced in the diagnosis and treatment of allergic diseases?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient have persistent and moderate-to-severe symptoms of allergic rhinitis (persistent symptoms are defined as symptoms presenting at least 4 days a week or for at least 4 weeks, and moderate-to-severe symptoms include one or more of the following items: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work)?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does patient have a current claim or prescription for auto-injectable epinephrine?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INITIAL CRITERIA (CONTINUED)

5. Is the patient at least 18 years of age?

   If yes, **approve for 12 months by HICL with a quantity limit of #1 tablet (12 Amb a 1-U) per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

INITIAL DENIAL TEXT: The guideline named **ALLERGEN EXTRACT-SHORT RAGWEED POLLEN (Ragwitek)** requires a diagnosis of short ragweed pollen-induced allergic rhinitis and a positive skin prick test or in vitro testing for pollen-specific IgE antibodies for short ragweed pollen; product must be prescribed or recommended by an allergist, immunologist, or other physician experienced in the diagnosis and treatment of allergic diseases; presentation of persistent and moderate-to-severe symptoms of allergic rhinitis; age of at least 18 years old; and a current claim or prescription for auto-injectable epinephrine.

RENEWAL CRITERIA

1. Has the patient experienced an improvement in signs and symptoms of allergic rhinitis from baseline?

   If yes, **approve for 12 months by HICL with a quantity limit of #1 tablet (12 Amb a 1-U) per day.**
   If no, do not approve.
   DENIAL TEXT: The guideline named **ALLERGEN EXTRACT-SHORT RAGWEED POLLEN (Ragwitek)** requires that the patient has experienced an improvement in signs and symptoms of allergic rhinitis from baseline.

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RATIONALE

Promote appropriate utilization of Ragwitek based on FDA approved indication, dosage, and guidelines adopted from ARIA (Allergic Rhinitis and its Impact on Asthma).

Ragwitek is a ragweed allergen-specific immunotherapy agent with FDA approval for sublingual use. The approval of oral allergen immunotherapy for allergic rhinitis provides a convenient and safe alternative to customary allergy shots. Ragwitek improves symptoms of allergic rhinoconjunctivitis and reduces use of rescue medication in adults. Allergen immunotherapy should be considered in patients who have persistent and moderate to severe symptoms despite pharmacotherapy, patients who experience intolerable side effects to medications, and those desiring to limit cost burden associated with chronic medication use. According to ARIA guidelines, persistent symptoms are defined as symptoms presenting at least 4 days a week or for at least 4 weeks, and moderate to severe symptoms include of one or more of the following items: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work.

Side effects are considered mild, with the majority of adverse events involving throat irritation (16.6% Ragwitek, 3.3% placebo), oral pruritus (10.9% Ragwitek, 2.0% placebo), ear pruritus (10.4% Ragwitek, 1.1% placebo), and oral paresthesia (10.1% Ragwitek, 4.0% placebo). One subject (1/1057, 0.1%) who received Ragwitek experienced anaphylaxis which led to discontinuation from the trial. The subject fully recovered after treatment with epinephrine, antihistamines, and oral corticosteroids. There were no reports of death during clinical trials.

Ragwitek has a black block warning that cites the following: Ragwitek can cause life-threatening allergic reactions such as anaphylaxis and severe laryngopharyngeal restriction; Do not administer Ragwitek to patients with severe, unstable or uncontrolled asthma; Observe patients in the office for at least 30 minutes following the initial dose; Prescribe auto-injectable epinephrine, instruct and train patients on its appropriate use, and instruct patients to seek immediate medical care upon its use; Ragwitek may not be suitable for patients with certain underlying medical conditions that may reduce their ability to survive a serious allergic reaction; Ragwitek may not be suitable for patients who may be unresponsive to epinephrine or inhaled bronchodilators, such as those taking beta-blockers.

DOSAGE

For adults 18 through 65 years of age, the dose is 1 tablet (12 Amb a 1-U) daily.

FDA APPROVED INDICATIONS

Ragwitek (short ragweed pollen extract) approved and indicated for the treatment of short ragweed pollen-induced allergic rhinitis, with or without conjunctivitis, confirmed by a positive skin prick test or in vitro testing for pollen-specific IgE antibodies for short ragweed pollen in adults 18 years through 65 years of age.

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REFERENCES

- Brozek JL, Bousquet J, Baena-Cagnani CE, Bonini S, Canonica GW, Casale TB, et al. Allergic Rhinitis and Its Impact on Asthma (ARIA) guidelines: 2010 revision. J Allergy Clin Immunol. 2010;126:466–476.
- Merck, Sharp & Dohme Corp. Ragwitek Package Insert. Whitehouse Station, NJ. April 2014.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/18
Created: 05/14
Client Approval: 02/18
P&T Approval: 01/18