Ragwitek

Description

Ragwitek (Short Ragweed Pollen Allergen Extract)

Background
Ragwitek is a short ragweed pollen extract formulated into a daily sublingual tablet used to treat short ragweed pollen-induced hay fever / allergies that can cause sneezing, runny or stuffy nose and watery eyes (1).

Regulatory Status
FDA-approved indication: Ragwitek is an allergen extract indicated as immunotherapy for the treatment of short ragweed pollen-induced allergic rhinitis, with or without conjunctivitis, confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for short ragweed pollen (1).

Ragwitek has a boxed warning concerning systemic allergic reactions including anaphylaxis and laryngopharyngeal swelling which may be life threatening. The initial dose of Ragwitek must be administered in a healthcare setting under the supervision of a physician and they must be monitored for at least 30 minutes to watch for signs and symptoms of life-threatening systemic or local allergic reaction. If the patient tolerates the first dose, subsequent doses may be taken at home. The prescriber should prescribe and an auto-injectable epinephrine to patients receiving Ragwitek with instruction on how to recognize the signs and symptoms of a severe allergic reaction and in the proper use of emergency auto-injectable epinephrine. Instruct patients to seek immediate medical care upon use of auto-injectable epinephrine and to stop treatment with Ragwitek (1).
Ragwitek is contraindicated in patients with severe, unstable or uncontrolled asthma (rescue inhaler use greater than 2 days or more per week; significantly impaired activity levels due to troublesome symptoms), a history of any severe systemic allergic reaction or severe local reaction after taking any sublingual allergen immunotherapy (1).

Ragwitek has a boxed warning that therapy might not be suitable for patients with certain underlying medical conditions or who may be unresponsive to epinephrine or inhaled bronchodilators, such as patients on beta-blockers (1).

Sublingual tablet immunotherapy is associated with eosinophilic esophagitis. Ragwitek is contraindicated in patients with eosinophilic esophagitis (1).

Concomitant dosing of Ragwitek with other allergen immunotherapy may increase the likelihood of local or systemic adverse reactions to either subcutaneous or sublingual allergen immunotherapy (1).

The safety and effectiveness of Ragwitek in patients younger than 18 years of age or older than 65 years of age have not been established (1).

**Related policies**
Grastek, Oralair

**Policy**

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Ragwitek may be considered **medically necessary** in patients 18 through 65 years of age for the treatment of short ragweed pollen-induced allergic rhinitis confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for short ragweed pollen and if the conditions indicated below are met.

Ragwitek may be considered **investigational** inpatients under 18 years of age or older than 65 years of age or patients and for all other indications.

**Prior-Approval Requirements**

**Age**

18 through 65 years of age
Diagnosis

Patient must have the following:

Short ragweed pollen-induced allergic rhinitis

AND ALL of the following:
1. Confirmation with either a positive skin test or in vitro testing for pollen-specific IgE antibodies for short ragweed pollen
2. Physician has adequate training and experience in the treatment of allergic diseases.
3. Patient has shown unacceptable response to at least one oral or intranasal steroid and at least one oral antihistamine.
4. Absence of severe, unstable or uncontrolled asthma (rescue inhaler use greater than 2 days or more per week; significantly impaired activity levels due to troublesome symptoms)
5. Absence of eosinophilic esophagitis
6. Auto-injectable epinephrine has been prescribed and the patient instructed in its use
7. Will NOT be used with other allergen immunotherapies
8. NO history of severe local reaction to sublingual allergen immunotherapy

Prior – Approval Renewal Requirements

Age
18 through 65 years of age

Diagnosis

Patient must have following:

Short ragweed pollen-induced allergic rhinitis

AND ALL of the following:
1. Absence of severe, unstable or uncontrolled asthma (rescue inhaler use greater than 2 days or more per week; significantly impaired activity levels due to troublesome symptoms)
2. Absence of eosinophilic esophagitis
3. Will NOT be used with other allergen immunotherapies
Policy Guidelines

Pre - PA Allowance
None

Prior - Approval Limits

<table>
<thead>
<tr>
<th>Quantity</th>
<th>90 tablets per 90 days</th>
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<tr>
<td>Duration</td>
<td>12 months</td>
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Prior – Approval Renewal Limits
Same as above

Rationale

Summary
Ragwitek is an allergen extract used to treat short ragweed pollen-induced allergic rhinitis with or without conjunctivitis confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for short ragweed pollen. The safety and effectiveness of Ragwitek in patients younger than 18 years of age or older than 65 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate and cost effective use of Ragwitek while maintaining optimal therapeutic outcomes.

References

Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>July 2014</td>
<td>New Policy Addition</td>
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<tr>
<td>September 2014</td>
<td>Annual review and reference update</td>
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<tr>
<td></td>
<td>Addition of no history of severe local reaction to sublingual allergen immunotherapy and clarification of uncontrolled asthma per SME</td>
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<tr>
<td></td>
<td>Age requirement changed to 18 years to 65 years of age</td>
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<tr>
<td>December 2014</td>
<td>Annual review and reference update</td>
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<tr>
<td>December 2015</td>
<td>Annual editorial review</td>
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<td>Date</td>
<td>Event</td>
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| September 2016 | Annual editorial review and reference update  
|               | Policy code changed from 5.08.34 to 5.20.05 |
| December 2017  | Annual editorial review and reference update  
|               | Addition of no dual therapy to renewal criteria |
| November 2018  | Annual review and reference update         |
| December 2019  | Annual review                              |

**Keywords**

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 6, 2019 and is effective on January 1, 2020.