

## Clinical Policy: Short Ragweed Pollen Allergen Extract (Ragwitek)

Reference Number: CP.PMN.83

Effective Date: 11.16.16

Last Review Date: 08.19

[Revision Log](#)

Line of Business: Commercial, Medicaid

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

### Description

Short ragweed pollen allergen extract (Ragwitek®) is an allergen extract.

### FDA Approved Indication(s)

Ragwitek is 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. Ragwitek is approved for use in adults 18 through 65 years of age.

Ragwitek is not indicated for the immediate relief of allergic symptoms.

### Policy/Criteria

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of health plans affiliated with Centene Corporation® that Ragwitek is **medically necessary** when the following criteria are met:

#### I. Initial Approval Criteria

##### A. Allergic Rhinitis (must meet all):

1. Diagnosis of short ragweed pollen-induced allergic rhinitis;
2. Prescribed by or in consultation with an allergist or immunologist;
3. Age  $\geq$  18 years and  $\leq$  65 years;
4. Confirmation of a positive skin test or in vitro testing for pollen-specific IgE antibodies for short ragweed pollen;
5. Failure of one intranasal corticosteroid, unless all are contraindicated or clinically significant adverse effects are experienced;
6. Failure of one oral antihistamine at up to maximally indicated doses, unless all are contraindicated or clinically significant adverse effects are experienced;
7. Dose does not exceed 1 tablet per day.

##### Approval duration:

**Medicaid** – 12 months

**Commercial** – Length of Benefit

**B. Other diagnoses/indications**

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial and CP.PMN.53 for Medicaid.

**II. Continued Therapy**

**A. Allergic Rhinitis** (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 1 tablet per day.

**Approval duration:**

**Medicaid** – 12 months

**Commercial** – Length of Benefit

**B. Other diagnoses/indications** (must meet 1 or 2):

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

**Approval duration: Duration of request or 12 months (whichever is less);** or

2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial and CP.PMN.53 for Medicaid.

**III. Diagnoses/Indications for which coverage is NOT authorized:**

- A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial and CP.PMN.53 for Medicaid or evidence of coverage documents.

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

FDA: Food and Drug Administration

*Appendix B: Therapeutic Alternatives*

*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.*

| Drug Name   | Dosing Regimen   | Dose Limit/<br>Maximum Dose |
|---|--|-----------------------------|
| OTC loratadine<br>(Claritin®)                       | 2 to 5 years: 5 mg PO QD<br>≥ 6 years: 10 mg PO QD     | 10 mg/day                   |
| OTC loratadine-D<br>(Claritin-D® 12 and<br>24 hour) | ≥ 12 years: 1 tablet PO BID (12 hr) QD<br>(24 hr)      | 10 mg/day                   |
| OTC cetirizine<br>(Zyrtec®)                         | 2 to 5 years: 2.5-5 mg PO QD<br>≥ 6 years: 10 mg PO QD | 10 mg/day                   |

| Drug Name  | Dosing Regimen   | Dose Limit/<br>Maximum Dose   |
|--|--|---|
| OTC fexofenadine (Allegra Allergy <sup>®</sup> )       | 6-months to 2 years: 15 mg PO QD<br>2 to 11 years: 30 mg PO QD<br>≥ 12 years: 60 mg PO BID or 180 mg PO QD | 180 mg/day  |
| fluticasone propionate (Flonase <sup>®</sup> )         | ≥ 4 years: 1-2 sprays each nostril QD<br>≥ 12 years: 1-2 sprays each nostril QD                            | 2 sprays each nostril/day   |
| triamcinolone acetonide (Nasacort AQ <sup>®</sup> )    | 2-11 years: 1 spray each nostril QD<br>≥ 12 years: 1-2 sprays each nostril QD                              | 2-11 years: 1 spray each nostril/day<br>> 12 years: 2 sprays each nostril/day |
| mometasone furoate monohydrate (Nasonex <sup>®</sup> ) | 2-11 years: 1 spray each nostril QD<br>≥ 12 years: 2 sprays each nostril QD                                | 2-11 years: 1 spray each nostril/day<br>> 12 years: 2 sprays each nostril/day |

*Therapeutic alternatives are listed as Brand name<sup>®</sup> (generic) when the drug is available by brand name only and generic (Brand name<sup>®</sup>) when the drug is available by both brand and generic.*

*Appendix C: Contraindications/Boxed Warnings*

- Contraindication(s): severe, unstable or uncontrolled asthma; history of eosinophilic esophagitis; history of any severe systemic allergic reaction or any severe local reaction to sublingual allergen immunotherapy; hypersensitivity to any of the inactive ingredients contained in this product
- Boxed warning(s): severe allergic reactions

**V. Dosage and Administration**

| Indication                                     | Dosing Regimen   | Maximum Dose |
|--|--|--------------|
| Short ragweed pollen-induced allergic rhinitis | One tablet SL QD<br><br>Treatment should be initiated at least 12 weeks before the expected onset of ragweed pollen season and continue treatment throughout the season. | 1 tablet/day |

**VI. Product Availability**

Tablets: 12 Amb a 1-Unit (Amb a 1-U)

**VII. References**

1. Ragwitek Prescribing Information. Whitehouse Station, NJ: Merck Sharp & Dohme Corp.; April 2017. Available at: <https://www.ragwitek.com/>. Accessed April 22, 2019.
2. Wallace DV, Dykewicz MS, Oppenheimer J et al. Pharmacologic treatment of seasonal allergic rhinitis: synopsis of guidance from the 2017 Joint Task Force on Practice Parameters. *Ann Intern Med.* 2017 Dec 19;167(12):876-881. doi: 10.7326/M17-2203.

3. Seidman MD, Gurgel RK, Lin SY, et al. Clinical practice guideline: Allergic rhinitis. Otolaryngol Head Neck Surg. 2015 Feb;152(1 Suppl):S1-43. doi: 10.1177/0194599814561600.
4. Wallace DV, Dykewicz MS, Bernstein DI, Blessing-Moore J, Cox L, Khan DA, Lang DM, Nicklas RA, Oppenheimer J, Portnoy JM, Randolph CC, Schuller D, Spector SL, Tilles SA, Joint Task Force on Practice, American Academy of Allergy, Asthma & Immunology, American College of Allergy, Asthma and Immunology, Joint Council of Allergy, Asthma and Immunology. The diagnosis and management of rhinitis: an updated practice parameter. J Allergy Clin Immunol. 2008;122(2 Suppl):S1-84.
5. Cox L, Nelson H, Lockey R, et al. Allergen immunotherapy: a practice parameter third update. J Allergy Clin Immunol. 2011 Jan;127(1 Suppl):S1-55.
6. Brozek, JL, Bousquet J, Agache I et al. Allergic rhinitis and its impact on asthma (ARIA) guidelines-2016 revision. J Allergy Clin Immunol. 2017 Oct;140(4):950-958. doi: 10.1016/j.jaci.2017.03.050.

| Reviews, Revisions, and Approvals   | Date     | P&T Approval Date |
|---|----------|-------------------|
| Converted to new template. Minor changes to verbiage and grammar. References updated.   | 01.12.17 | 11.17             |
| 3Q 2018 annual review: polices combined for Medicaid and Commercial (CP.CPA.111); added age; Medicaid: increased approval duration to 12 months; Commercial: removed leukotriene modifiers as pdl alternative per 2017 guidelines; references reviewed and updated. | 03.28.18 | 08.18             |
| 3Q 2019 annual review: no significant changes; corrected age restriction from < 65 years to ≤ 65 years per PI; references reviewed and updated.   | 04.22.19 | 08.19             |

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and

limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

**Note:**

**For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

©2016 Centene Corporation. All rights reserved. All materials are exclusively owned by Centene Corporation and are protected by United States copyright law and international copyright law. No part of this publication may be reproduced, copied, modified, distributed, displayed, stored in a retrieval system, transmitted in any form or by any means, or otherwise published without the prior written permission of Centene Corporation. You may not alter or remove any trademark, copyright or other notice contained herein. Centene® and Centene Corporation® are registered trademarks exclusively owned by Centene Corporation.