## Prior Authorization Review Panel

**CHC-MCO Policy Submission**

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

| | |
|---|---|
| **Plan: PA Health & Wellness** | **Submission Date: 11/1/2018** |
| **Policy Number: PA.CP.PMN.83** | **Effective Date: 10/17/2018**<br>**Revision Date: 10/17/2018** |
| **Policy Name: Short Ragweed Pollen Allergen Extract (Ragwitek)** | **HC Approval Date:** |

**Type of Submission – Check all that apply:**

- ✓ **New Policy**
- ☐ **Revised Policy***
- ☐ **Annual Review – No Revisions**
- ☐ **Attestation of HC PARP Policy –** *This option should only be used during Readiness Review for Community HealthChoices. The policy must be identical to the PARP approved policy for the HealthChoices Program, with the exception of revisions/clarifications adding the term "Community HealthChoices" to the policy.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

**Please provide any changes or clarifying information for the policy below:**

**New Policy created.**

| | |
|---|---|
| **Name of Authorized Individual (Please type or print):**<br><br>**Francis G. Grillo, MD** | **Signature of Authorized Individual:** |

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

Reference Number: PA.CP.PMN.83
Effective Date: 10.17.18
Last Review Date: 10.17.18 Revision Log

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

**Commented [ZL1]:** Please be aware that there are currently no products eligible for coverage by MA.

**Commented [PBN2R1]:** We will remove from formulary

**Commented [ZL3R1]:** Is the prior authorization policy being withdrawn as well? If so please note in DocuShare.

**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.

**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 PA Health & Wellness® 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 ≥ 18 years and < 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 daily.

**Approval duration:** 12 months

**B. Other diagnoses/indications**

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

**II. Continued Therapy**

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

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 1 tablet daily.

**Approval duration: 12 months**

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

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies.
   **Approval duration: Duration of request or 12 months (whichever is less)**; or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

**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 – PA.CP.PMN.53.

**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/ Maximum Dose |
|---|---|---|
| OTC loratadine (Claritin®) | 2 to 5 years: 5 mg PO QD<br>≥ 6 years: 10 mg PO QD | 10 mg/day |
| OTC loratadine-D (Claritin-D® 12 and 24 hour) | ≥ 12 years: 1 tablet PO BID (12 hr) QD (24 hr) | 10 mg/day |
| OTC cetirizine (Zyrtec®) | 2 to 5 years: 2.5-5 mg PO QD<br>≥ 6 years: 10 mg PO QD | 10 mg/day |
| OTC fexofenadine (Allegra Allergy®) | 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®) | ≥ 4 years: 1-2 sprays each nostril QD<br>≥ 12 years: 1-2 sprays each nostril QD | 2 sprays each nostril/day |

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| triamcinolone acetonide (Nasacort AQ®) | 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 |
| Nasonex® (mometasone furoate monohydrate) | 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® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.*

*Appendix C: Contraindications*

- Severe, unstable or uncontrolled asthma
- A history of eosinophilic esophagitis

## V. Dosage and Administration

| Indication | Dosing Regimen | Maximum Dose |
|---|---|---|
| Short ragweed pollen-induced allergic rhinitis | One tablet sublingually daily.<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 per 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.; March 2017. Available at: https://www.ragwitek.com/. Accessed March 28, 2018.
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 |
|---|---|---|
| Policy Created | 10/18 | |