Clinical Policy Title:	short ragweed pollen allergen extract
Policy Number:	RxA.272
Drug(s) Applied:	Ragwitek®
Original Policy Date:	02/07/2020
Last Review Date:	06/10/2021
Line of Business Policy Applies to:	All lines of business

Background

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

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
short ragweed pollen allergen extract (Ragwitek®)	Short ragweed pollen-induced allergic rhinitis	One tablet SL once daily 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

Dosage Forms

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

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

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 per day.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

II. Continued Therapy Approval

A. Allergic Rhinitis (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
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
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
OTC loratadine (Claritin®)	2 to 5 years: 5 mg PO once daily ≥ 6 years: 10 mg PO once daily	10 mg/day
OTC loratadine-D (Claritin-D® 12 and 24 hour)	≥ 12 years: 1 tablet PO BID (12 hr) once daily (24 hr)	10 mg/day
OTC cetirizine (Zyrtec®)	2 to 5 years: 2.5-5 mg PO once daily ≥ 6 years: 10 mg PO once daily	10 mg/day
OTC fexofenadine (Allegra Allergy®)	6-months to 2 years: 15 mg PO once daily 2 to 11 years: 30 mg PO once daily ≥ 12 years: 60 mg PO BID or 180 mg PO once daily	180 mg/day
fluticasone propionate	4 to 11 years: 1-2 sprays each nostril once daily	2 sprays each nostril/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
(Flonase Allergy Relief®, Flonase Sensimist®)	≥ 12 years: 1-2 sprays each nostril once daily 2 to 11 years: 1-2 sprays each nostril once daily ≥ 12 years: 1-2 sprays each nostril once daily	
triamcinolone acetonide (Nasacort®)	2-11 years: 1 spray each nostril once daily ≥ 12 years: 1-2 sprays each nostril once daily	2-11 years: 1 spray each nostril/day > 12 years: 2 sprays each nostril/day
mometasone furoate monohydrate (Nasonex®, Sinuva®)	2-11 years: 1 spray each nostril once daily ≥ 12 years: 2 sprays each nostril once daily	2-11 years: 1 spray each nostril/day > 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/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 – 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.

APPENDIX D: General Information

- Not applicable

References

1. Ragwitek® Prescribing Information. Whitehouse Station, NJ: Merck Sharp & Dohme Corp.; June 2019. Available at: https://www.ragwitek.com/. Accessed February 24, 2021.
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.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established	01/2020	02/07/2020
Policy was reviewed: 1. Clinical Policy Title was updated. 2. Drug(s) Applied was updated. 3. Line of Business Policy Applies to was updated. 4. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..." 5. Commercial approval duration and Medicaid approval duration updated. 6. Updated APPENDIX B: Therapeutic Alternatives to exclude discontinued drugs from the list (Nasacort AQ®, Flonase®) and include newly added drugs in the list (Sinuva®, Nasacort®, Flonase Allergy Relief®, Flonase Sensimist®). 7. Updated Appendix C – added unstable asthma for contraindications; added "RAGWITEK® can cause life-threatening allergic reactions ssuch as anaphylaxis and severe laryngopharyngeal restriction."for Boxed Warning. 8. References were updated.	07/03/2020	09/14/2020
Policy was reviewed: 1. Last Review Date was updated. 2. Clinical policy verbiage was updated to "The	02/24/2021	06/10/2021

provision of provider samples does not guarantee….”. 3. APPENDIX B: Therapeutic Alternatives verbiage was updated to "Below are suggested therapeutic alternatives based on clinical guidance...." 4. APPENDIX C: Boxed Warnings were updated. 5. References were updated.		