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|  <p>JOHNS HOPKINS MEDICINE JOHNS HOPKINS HEALTHCARE</p> | Johns Hopkins HealthCare LLC Pharmacy Public Pharmacy Management Drug Policies | <i>Policy Number</i> | MEDS087 | |
| | | <i>Effective Date</i> | 01/01/2015 | |
| | | <i>Review Date</i> | 01/21/2015 | |
| | <i>Subject</i> | Oral Immunotherapy Agents (Oralair, Grastek and Ragwitek) | <i>Revision Date</i> | 12/07/2021 |
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This document applies to the following Participating Organizations:

Priority Partners

Keywords: Grastek, Immunotherapy, Oralair, Ragwitek

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I. POLICY

- A. Oral immunotherapy agents will require prior authorization to ensure this medication is used only when clinically appropriate. All other necessary procedures for initiation of prior authorization review can be found in policy PHARM 20.
1. PPMCO members are subject to the Priority Partners formulary, available at www.ppmco.org.
 2. USFHP members are subject to prior authorization criteria, step-edits and days-supply limits outlined in the Tricare Policy Manual. Tricare Policy supersedes JHHC Medical/Pharmacy Policies. Tricare limits may be accessed at: http://pec.ha.osd.mil/formulary_search.php?submenuheader=1

II. POLICY CRITERIA


- A. Oral Immunotherapy agents may be approved for patients meeting the following:
1. Patient is between 5 years and 65 years of age
 2. Documentation has been submitted showing the following:
 - a. Allergic rhinitis has been confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies
 - b. Patient has had trials and inadequate responses to all of the following:
 - I. montelukast
 - II. one oral antihistamine
 - III. one intranasal steroid
 - c. The requested oral immunotherapy agent will be used for its approved grass pollen-induced allergic rhinitis:
 - I. Oralair: Sweet Vernal, Orchard, Perennial Rye, Timothy, or Kentucky Blue Grass Mixed Pollens Allergen
 - II. Grastek: Timothy grass or cross-reactive grass pollens
 - III. Ragwitek: short Ragweed pollen

III. AUTHORIZATION PERIOD/LIMITATIONS

- A. Patients may be approved for the term of enrollment

IV. EXCLUSIONS

- A. Known hypersensitivity to any oral extracts and their components
- B. Members with severe, unstable, or uncontrolled asthma
- C. Members who are non-responsive to epinephrine or inhaled bronchodilators

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- D. Concomitant allergen immunotherapy
- E. The use of physician samples, or manufacturer product discounts, does not guarantee coverage under the provisions of the medical and/or pharmacy benefit. All pertinent criteria must be met in order to be eligible for benefit coverage.

V. REFERENCES

1. Oralair [prescribing information]. Lenoir, NC: Greer Laboratories; November 2018
2. Grastek [prescribing information]. Horsholm, Denmark: ALK-Abello A/S; December 2019
3. Ragwitek [prescribing information]. Horsholm, Denmark: ALK-Abello A/S; April 2021

VI. APPROVALS

Signature on file at JHHC

| DATE OF REVISION | SUMMARY OF CHANGE |
|-------------------------|--------------------------------------------------------|
| 06/19/2017 | Clarified clinical criteria |
| 07/27/2017 | Updated Exclusions section regarding physician samples |
| 07/01/2018 | Removed EHP Line of Business |
| 12/07/2021 | Updated criteria layout |

Review/Revision Dates: 07/01/2014, 01/21/2015, 06/19/2017, 07/27/2017, 07/01/2018, 12/02/2021, 12/07/2021