

Drug Policy

Policy:	Sublingual Allergen Extract Immunotherapy Prior Approval <ul style="list-style-type: none"> • Odactra (house dust mite) • Grastek (timothy grass pollen) • Ragwitek (short ragweed pollen) • Oralair (mixed grass pollens) 	Annual Review Date: 03/21/2024 Last Revised Date: 03/21/2024
----------------	---	---

OVERVIEW

Odactra is a house dust mite (HDM) allergen extract sublingual (SL) tablet indicated as immunotherapy for the treatment of patients with HDM-induced allergic rhinitis with or without conjunctivitis (AR/C). Odactra is indicated in patients 12 to 65 years of age with AR/C confirmed by confirmed by *in vitro* testing for immunoglobulin E (IgE) antibodies to HDM or a positive skin test to licensed HDM allergen extracts. Odactra is not indicated for the immediate relief of allergy symptoms. Oralair (mixed grass pollens allergens extract) is a sublingual allergen extract tablet indicated as immunotherapy for the treatment of grass pollen-induced allergic rhinitis with or without conjunctivitis. Ragwitek (short ragweed pollen allergen extract) is a sublingual allergen extract indicated as immunotherapy for the treatment of short ragweed pollen-induced allergic rhinitis with or without conjunctivitis. Grastek (timothy grass pollen allergen extract) is a sublingual allergen extract tablet indicated as immunotherapy for the treatment of grass pollen-induced allergic rhinitis with or without conjunctivitis. Grastek and Oralair is indicated in patients 5 through 65 years of age.

POLICY STATEMENT

Prior authorization is recommended for pharmacy benefit coverage of Odactra (house dust mite), Grastek (timothy grass pollen), Ragwitek (short ragweed pollen), and Oralair (mixed grass pollens). Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Odactra, Grastek, Ragwitek, and Oralair as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Odactra, Grastek, Ragwitek, and Oralair be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Odactra, Grastek, Ragwitek, and Oralair is recommended in those who meet the following criteria:

FDA-Approved Indications

Drug Policy

Allergen - Induced Allergic Rhinitis (AR). Approve for 1 year if the patient meets ALL of the criteria below for the requested corresponding medication:

Odactra

- The patient has a positive skin test response or a positive *in vitro* test (i.e., a blood test for allergen-specific IgE antibodies) to house dust mite allergen extracts AND
- The patient is ≥ 12 years of age and less than 65 years of age; AND
- The medication is prescribed by or in consultation with an allergist, immunologist, or an otolaryngologist (ear, nose and throat [ENT]) physician specialist; AND
- Patient has tried and failed: nasal or oral antihistamines and nasal or oral corticosteroids; AND
- First dose will be given under the supervision of a physician with experience in the diagnosis and treatment of severe allergic reactions; AND
- Epinephrine rescue auto-injection (e.g. Epipen) is available to patient at home; AND
- **None** of the following are present:
 1. Severe, unstable or uncontrolled asthma; OR
 2. History of any severe systemic allergic reaction or any severe local reaction to sublingual allergen immunotherapy; OR
 3. History of eosinophilic esophagitis.

Grastek

- Diagnosis has been confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies to timothy grass or cross-reactive grass pollens; AND
- The patient is ≥ 5 years of age and less than 65 years of age; AND
- Treatment will be initiated approximately 3 months before the start of grass pollen season, and will be continued throughout the season; AND
- The medication is prescribed by or in consultation with an allergist, immunologist, or an otolaryngologist (ear, nose and throat [ENT]) physician specialist; AND
- Patient has tried and failed: nasal or oral antihistamines and nasal or oral corticosteroids; AND
- First dose will be given under the supervision of a physician with experience in the diagnosis and treatment of severe allergic reactions; AND
- Epinephrine rescue auto-injection (e.g. Epipen) is available to patient at home; AND
- **None** of the following are present:
 1. Severe, unstable or uncontrolled asthma; OR
 2. History of any severe systemic allergic reaction or any severe local reaction to sublingual allergen immunotherapy; OR
 3. History of eosinophilic esophagitis.

Ragwitek

- Diagnosis has been confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies to short ragweed pollen; AND
- The patient is ≥ 5 years of age and less than 65 years of age; AND

Drug Policy

- The medication is prescribed by or in consultation with an allergist, immunologist, or an otolaryngologist (ear, nose and throat [ENT]) physician specialist; AND
- Treatment will be initiated approximately 3 months before the start of ragweed pollen season and will be continued throughout the season; AND
- Patient has tried and failed: nasal or oral antihistamines and nasal or oral corticosteroids; AND
- First dose will be given under the supervision of a physician with experience in the diagnosis and treatment of severe allergic reactions; AND
- Epinephrine rescue auto-injection (e.g. Epipen) is available to patient at home; AND
- **None** of the following are present:
 1. Severe, unstable or uncontrolled asthma; OR
 2. History of any severe systemic allergic reaction or any severe local reaction to sublingual allergen immunotherapy; OR
 3. History of eosinophilic esophagitis.

Oralair

- Diagnosis has been confirmed by positive skin test or in vitro testing for grass pollen-specific IgE antibodies to sweet vernal, orchard, perennial rye, timothy, or Kentucky blue grasses; AND
- The patient is ≥ 5 years of age and less than 65 years of age; AND
- Treatment will be initiated approximately 4 months before the start of grass pollen season and will be continued throughout the season; AND
- The medication is prescribed by or in consultation with an allergist, immunologist, or an otolaryngologist (ear, nose and throat [ENT]) physician specialist; AND
- Patient has tried and failed: nasal or oral antihistamines and nasal or oral corticosteroids; AND
- First dose will be given under the supervision of a physician with experience in the diagnosis and treatment of severe allergic reactions; AND
- Epinephrine rescue auto-injection (e.g. Epipen) is available to patient at home; AND
- **None** of the following are present:
 1. Severe, unstable or uncontrolled asthma; OR
 2. History of any severe systemic allergic reaction or any severe local reaction to sublingual allergen immunotherapy; OR
 3. History of eosinophilic esophagitis.

Initial Approval/ Extended Approval.

A) *Initial Approval:* 1 year (365 days)

B) *Extended Approval:* 1 year (365 days)

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Sublingual Allergen Extract Immunotherapy has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

Drug Policy

1. **Concurrent use of Odactra, Ragwitek, Oralair, Grastek with subcutaneous (SC) allergen immunotherapy (e.g., allergy shots) or sublingual (SL) allergen immunotherapy** (e.g., Grastek® [Timothy grass pollen allergen extract sublingual tablets], Oralair® [Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass mixed pollens allergen extract sublingual tablets], Ragwitek® [short ragweed pollen allergen extract sublingual tablets]). The efficacy and safety of Odactra have not been evaluated in patients who are receiving concomitant allergen immunotherapy. Approved product labeling for Odactra states that concomitant dosing with other allergen immunotherapy may increase the risk of local or systemic AEs to either the SC or SL allergen immunotherapy.
2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Odactra® allergen extract tablet for sublingual use [prescribing information]. Whitehouse Station, NJ: Merck & Co.; March 2017.
2. Nolte H, Bernstein DI, Nelson HS, et al. Efficacy of house dust mite sublingual immunotherapy tablet in North American adolescents and adults in a randomized, placebo-controlled trial. *J Allergy Clin Immunol.* 2016;138(6):1631-1638.
3. Demoly P, Emminger W, Rehm D, et al. Effective treatment of house dust mite-induced allergic rhinitis with 2 doses of the SQ HDM SLIT-tablet: results from a randomized, double-blind, placebo-controlled phase III trial. *J Allergy Clin Immunol.* 2016;137(2):444-451.
4. Cox L, Nelson H, Lockey R, et al. Allergen immunotherapy: a practice parameter third update. *J Allergy Clin Immunol.* 2011;127(1):S1-S53.
5. Canonica GW, Cox L, Pawankar R, et al. Sub-lingual Immunotherapy World Allergy Organization Position Paper 2013 Update. *WAO Journal.* 2014;7(6):1-52.
6. Grastek® tablet for sublingual use [prescribing information]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp., Inc.; September 2016.
7. Oralair® tablet for sublingual use [prescribing information]. Lenoir, NC: Greer Laboratories, Inc.; December 2016.
8. Ragwitek™ tablet for sublingual use [prescribing information]. Whitehouse Station, NJ: Merck & Co., Inc.; March 2017.