

Pharmacy Policy Bulletin

Sublingual Immunotherapies – Medicare

Number: J-0402	Category: Prior Authorization
Line(s) of Business: <input type="checkbox"/> Commercial <input type="checkbox"/> Healthcare Reform <input checked="" type="checkbox"/> Medicare	Benefit(s): Not applicable
Region(s): <input type="checkbox"/> All <input type="checkbox"/> Delaware <input type="checkbox"/> New York <input checked="" type="checkbox"/> Pennsylvania <input checked="" type="checkbox"/> West Virginia	Additional Restriction(s): None

Drugs Products	<ul style="list-style-type: none"> • sweet vernal, orchard, perennial rye, timothy and Kentucky blue grass mixed pollens allergens extract (Oralair®) • timothy grass pollen allergen extract (Grastek®) • short ragweed pollen allergen extract (Ragwitek®)
FDA-Approved Indications:	<ul style="list-style-type: none"> • Oralair is approved for the treatment of allergic rhinitis (with or without allergic conjunctivitis) induced by grass pollen, specifically Sweet Vernal, Orchard, Perennial Rye, Timothy, or Kentucky Blue Grass. • Grastek is approved for the treatment of allergic rhinitis (with or without allergic conjunctivitis) induced by Timothy grass or cross-reactive grass pollens. • Ragwitek is approved for the treatment of allergic rhinitis (with or without allergic conjunctivitis) induced by short ragweed pollen.

Background:	<ul style="list-style-type: none"> • These medications are considered immunotherapy. The precise mechanism of the allergen immunotherapy is unknown. • Prescribing Considerations: <ul style="list-style-type: none"> ◦ The medication is being prescribed by an allergy specialist, otolaryngologist (ENT) physician, or immunologist
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Approval Criteria

- I. When a benefit, sublingual immunotherapy may be approved when the following criteria are met **(A. through E.)**:
 - A. The member has been diagnosed with allergic rhinitis of sufficient severity and is using one of the following **(1., 2., or 3.)**
 1. Oralair for Sweet Vernal, Orchard, Perennial Rye, Timothy, or Kentucky Blue Grass pollen **AND** is in between the ages of 10-65
 2. Grastek for Timothy grass pollen or cross reactive grass pollens (Sweet Vernal, Orchard, Perennial Rye, Timothy, Kentucky Blue Grass pollen, Redtop, or meadow fescue) **AND** is in between the ages of 5-65
 3. Ragwitek for ragweed pollen **AND** is in between the ages of 18-65
 - B. Allergic rhinitis with or without conjunctivitis has been confirmed by a pollen specific positive skin test OR in vitro testing for pollen-specific IgE antibodies
 - C. The member has a documented failure or experienced inadequate relief or intolerance to an intranasal steroid and has tried and failed or experienced an adverse effect to at least one oral non-sedating antihistamine, intranasal antihistamine, or intranasal anticholinergic agent
 - D. The member is not using any concomitant sublingual or subcutaneous immunotherapy
 - E. Documentation of a prescription for an epinephrine auto injector.

- II. For Medicare Part D beneficiaries, sublingual immunotherapies may be approved when used for a medically accepted indication as defined by the Centers for Medicare & Medicaid Services (CMS).

Limitations of Coverage

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- I. Members with severe, unstable or uncontrolled asthma
 - II. Members with certain underlying conditions who may not be able to survive a serious allergic reaction
 - III. Members who may be unresponsive to epinephrine or inhaled bronchodilators, such as those taking beta-blockers may not be suitable for these therapies
 - IV. Not indicated for immediate relief of allergy symptoms
 - V. Ragwitek and Oralair do not have data available regarding the safety of starting treatment during the pollen season, or restarting treatment after missing a dose
 - VI. Oralair treatment should not be initiated in-season but 4 months prior to allergy season, which is typically during the summer months, starting in May
 - VII. Ragwitek treatment should not be initiated in-season but 3 months prior to allergy season, which is typically during the fall months, starting in August
 - VIII. Grastek treatment should not be initiated in-season but 3 months prior to allergy season, which is typically during the summer months, starting in May
 - IX. Grastek will not be approved for over three consecutive years if used daily
 - X. The prescriber has documented monitoring of first dose in the office

Allergen immunotherapy or subcutaneous immunotherapy (SCIT) (also known as desensitization, hyposensitization, allergy injection therapy, or "allergy shots"), is the repeated administration of specific allergens to patients with immune globulin E (IgE)-mediated conditions. The aim is to modify or stop the allergy by reducing the strength of the IgE response. These products (injectable immunotherapy) are excluded under the pharmacy benefit. Refer to policy I-3 Allergy Immunotherapy for criteria associated with coverage under the medical benefit.

Authorization Duration

- Medicare Part D Plans: If approved, a 12 month authorization will be granted.

Automatic Approval Criteria

None

Version: J-0402-010

Effective Date Begin: 01/01/2019

Effective End Begin: 12/31/2019
Original Date: 08/19/2014
Review Date: 05/02/2018

References:

1. Oralair [Package insert]. Stallergenes S. A. Greer Labs Lenoir, NC. 2014.
2. Grastek [Package Insert]. Whitehouse Station, NJ: MERCK&Co. Inc. April 2017
3. Ragwitek [Package insert]. Merck Sharp & Dohme Corp. Whitehouse Station, Nj. March 2017.
4. Odactra [Package insert]. Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Whitehouse Station, NJ April 2017
5. Canonica, Giorgio Walter, et al. "Sublingual immunotherapy: World Allergy Organization position paper 2013 update." *World Allergy Organ J* (2014):
6. DRUGDEX System. New York: Thomson Reuters; 2018. Accessed March 2018.
7. Clinical Pharmacology. Tampa, FL: Gold Standard inc 2018. Accessed March 2018
8. Maloney, Jennifer, et al. "Efficacy and safety of grass sublingual immunotherapy tablet, MK-7243: a large randomized controlled trial." *Annals of Allergy, Asthma & Immunology* 112.2 (2014): 146-153.
9. "National Allergy Bureau." NAB Pollen Counts. American Academy of Allergy, Asthma & Immunology, 01 July 2014. <http://www.aaaai.org/global/nab-pollen-counts.aspx>

Pharmacy policies do not constitute medical advice, nor are they intended to govern physicians' prescribing or the practice of medicine. They are intended to reflect Highmark's coverage and reimbursement guidelines. Coverage may vary for individual members, based on the terms of the benefit contract.

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