Pharmacy Policy Bulletin

Sublingual Immunotherapies - Medicare	
Number: J-0402	**Category:** Prior Authorization
Line(s) of Business: ☐ Commercial ☐ Healthcare Reform ☑ Medicare	**Benefit(s):** Not applicable
Region(s): ☐ All ☐ Delaware ☐ New York ☑ Pennsylvania ☑ West Virginia	**Additional Restriction(s):** None

Drugs Products	• 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:	• 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:	• These medications are considered immunotherapy. The precise mechanism of the allergen immunotherapy is unknown. • Prescribing Considerations: ○ The medication is being prescribed by an allergy specialist, otolaryngologist (ENT) physician, or immunologist

Approval Criteria

When a benefit, sublingual immunotherapy may be approved when the following criteria are met (**1. through 5.)**:

1. The member has been diagnosed with allergic rhinitis of sufficient severity and is using one of the following **(a., b., or c.)**

a. Oralair for Sweet Vernal, Orchard, Perennial Rye, Timothy, or Kentucky Blue Grass pollen ***AND*** is in between the ages of 10-65

b. 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

c. Ragwitek for ragweed pollen ***AND*** is in between the ages of 18-65

2. 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

3. 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

4. The member is not using any concomitant sublingual or subcutaneous immunotherapy

5. Documentation of a prescription for an epinephrine auto injector.

Reauthorization:

Reauthorization requires documentation of improved allergy symptoms.

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

Limitations of Coverage

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 when starting therapy per limitations.

Example: Ragwitek can be used 3 months prior to allergy season and during allergy season. In the northeast, Ragwitek would be approved for 7 months starting no later than May and approved through October.

Automatic Approval Criteria

None

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References:

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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* 7.1 (2014):
6. DRUGDEX System. New York: Thomson Reuters; 2018. Accessed March 2018.
7. Clinical Pharmacology. Tampa, FL: Gold Standard inc 2018. Acessed 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

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