PRIOR AUTHORIZATION POLICY

POLICY: Allergen Immunotherapy – Grass Pollen Sublingual Products Prior Authorization Policy
- Grastek® (Timothy grass pollen allergen extract sublingual tablets – ALK-Abello)
- Oralair® (Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass mixed pollens allergen extract sublingual tablets – Stallergenes/Greer)

REVIEW DATE: 08/05/2020

OVERVIEW

Grastek and Oralair are grass pollen allergen extract sublingual tablets.[1,2] Grastek is a Timothy grass pollen allergen extract.[1] Oralair is a five-grass mixed pollen allergen extract.[2] Grastek and Oralair are indicated for:

- **Allergic rhinitis**, with or without conjunctivitis, that has been confirmed by a positive skin test or *in vitro* test for pollen-specific immunoglobulin E (IgE) antibodies for Timothy grass or cross reactive grass pollens (Grastek) or any of the five grasses contained in the product (Oralair). These products are indicated in patients 5 through 65 years of age.

Per product labeling, Grastek must be initiated 12 weeks before the expected onset of each grass pollen season and Oralair must be initiated 4 months before the expected onset of each grass pollen season.[1,2] Both must be continued throughout the season.

Clinical Efficacy

In clinical trials, therapy with the grass pollen sublingual immunoallergen agents prior to and during a single grass pollen season resulted in a 23% to 30% improvement in patients' Total Combined Score (TCS) [a measurement of both allergic rhinitis with or without conjunctivitis symptoms and relief medication use] compared with placebo.[1,2] Longer-term data demonstrate a 38% to 40% improvement in the TCS with these agents vs. placebo.

Guidelines

Numerous guidelines address allergic rhinitis and allergen immunotherapy. In general, allergen immunotherapy should be considered for patients with allergic rhinitis or allergic asthma and an inadequate response to medical therapy who have evidence of specific IgE antibodies to clinically relevant allergens.[3,4] Grass pollen sublingual immunotherapy tablets are recommended for both short-term and long-term benefit in grass pollen-induced allergic rhinitis with or without conjunctivitis.[5,6]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Grastek and Oralair. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

1. **Grass Pollen-Induced Allergic Rhinitis.** Approve for 1 year if the patient meets ALL of the following criteria (A, B and C):
   A) Patient is ≥ 5 years of age; AND
   B) The timing of prescribing meets ONE of the following criteria (i or ii):
      i. Grastek: Therapy is initiated 12 weeks prior to the expected onset of the grass pollen season or therapy is being dosed daily continuously for consecutive grass pollen seasons; OR
      ii. Oralair: Therapy is initiated 4 months prior to the expected onset of the grass pollen season; AND
   C) The diagnosis of grass pollen-induced allergic rhinitis is confirmed by meeting ONE of the following conditions (i or ii):
      i. Patient has a positive skin test response to a grass pollen from the Pooideae subfamily of grasses (this includes, but is not limited to: sweet vernal, Kentucky blue grass, Timothy grass, orchard, or perennial rye grass); OR
      ii. Patient has a positive *in vitro* test (i.e., a blood test) for allergen-specific immunoglobulin E (IgE) antibodies for a grass in the Pooideae subfamily of grasses (see examples above).

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Grastek and Oralair is not recommended in the following situations:

1. **Concurrent Use of Grastek or Oralair with Subcutaneous Allergen Immunotherapy (e.g., Allergy Shots) or Sublingual Allergen Immunotherapy (e.g., Odactra™ [house dust mite {*Dermatophagoides farina* and *Dermatophagoides pteronyssinus*} allergen extract sublingual tablets], Ragwitek® [short ragweed pollen allergen extract sublingual tablets]).** The efficacy of Grastek and Oralair has not been evaluated in patients who are receiving concomitant allergen immunotherapy.[1] Approved product labeling for both Grastek and Oralair states that concomitant dosing with other allergen immunotherapy may increase the risk of local or systemic adverse events to either subcutaneous or sublingual allergen immunotherapy. A Joint Practice Parameter specifically addressing sublingual immunotherapy (2017) highlights that no studies have evaluated the efficacy of multiple sublingual immunotherapy tablets administered together.[5] There is a need for further investigation to determine efficacy and optimal formulations for multi-allergen sublingual 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.

REFERENCES

1. Grastek® tablet for sublingual use [prescribing information]. Swindon, Wiltshire, United Kingdom: ALK-Abello A/S; December 2019.
2. Oralair® tablet for sublingual use [prescribing information]. Lenoir, NC: Greer Laboratories, Inc.; November 2018.
3. Cox L, Nelson H, Lockey R, et al. Allergen immunotherapy: a practice parameter third update. *J Allergy Clin Immunol.* 2011;127(1):S1-S53.
4. Seidman MD, Gurgel RK, Lin SY, et al. Clinical practice guideline: allergic rhinitis. *Otolaryngol Head Neck Surg.* 2015;152(IS):S1-S43.
5. Greenhawt M, Oppenheimer J, Nelson M, et al. Sublingual immunotherapy: a focused allergen immunotherapy practice parameter update. *Ann Allergy Asthma Immunol.* 2017;118:276-282.
6. Roberts G, Pfaar O, Akdis CA, et al. EAACI guidelines on allergen immunotherapy: allergic rhinoconjunctivitis. *Allergy.* 2018;73(4):765-798.