VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Allergen Immunotherapy

- 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)

TAC APPROVAL DATE: 07/10/2019

OVERVIEW

Grastek and Oralair are grass pollen allergen extract sublingual (SL) tablets indicated as immunotherapy for the treatment of patients 5 through 65 years of age with grass pollen-induced allergic rhinitis with or without conjunctivitis (AR/C).[1-2] Grastek, a Timothy grass pollen allergen extract, is indicated in patients with AR/C 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.[1] Oralair, a five-grass mixed pollens allergen extract, is indicated in patients with AR/C confirmed by a positive skin test or *in vitro* test for pollen-specific IgE antibodies for any of the five grasses contained in the product.[2] Grastek and Oralair are not indicated for the immediate relief of allergy symptoms. In clinical trials, therapy with the grass pollen SL 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 AR/C 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. The 2015 American Academy of Otolaryngology (AAO) and the 2011 Joint Taskforce of The American Academy of Allergy, Asthma, and Immunology (AAAAI), the American College of Allergy, Asthma, and Immunology (ACAAI), and the Joint Council of Allergy, Asthma and Immunology (JCAAI) Practice Parameter for Allergen Immunotherapy states that 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] The European Academy of Allergy and Clinical Immunology (EAACI) guidelines on allergen immunotherapy for allergic rhinitis (2018) make similar recommendations and also specifically recommend grass pollen SLIT tablets for both short-term and long-term benefit in grass pollen-induced AR/C.[21] In 2017, a Joint Practice Parameter specifically addressing SL immunotherapy was published.[5] FDA-approved SL immunotherapy agents, including Grastek and Oralair, are recommended to be used only for the treatment of AR/C and not for other off-label conditions.

POLICY STATEMENT

Prior authorization is recommended for prescription benefit coverage of the sublingual grass pollen immunoallergen extracts. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

1. **Grass Pollen-Induced Allergic Rhinitis (AR).** Approve for 1 year if the patient meets ALL of the following criteria (A, B and C):
   - **A)** The patient is ≥ 5 years of age;[1,6-8] AND
   - **B)** The timing of prescribing meets ONE of the following criteria (i or ii):[1,2]
     - **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 AR is confirmed by meeting ONE of the following conditions (i or ii):[6-20]
     - **i.** The 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.** The 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

Grastek and Oralair have 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. Rationale for non-coverage for these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

1. **Concurrent use of Grastek or Oralair with subcutaneous (SC) allergen immunotherapy (e.g., allergy shots) or sublingual (SL) 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 SC or SL allergen immunotherapy. A Joint Practice Parameter specifically addressing SL immunotherapy (2017) highlights that no studies have evaluated the efficacy of multiple SLIT tablets administered together.[5] There is a need for further investigation to determine efficacy and optimal formulations for multi-allergen SL 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

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OTHER REFERENCES UTILIZED

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HISTORY

Type of Revision	Summary of Changes*	TAC Approval Date
Annual Revision	No changes to criteria.	07/27/2016
Early Annual Revision	Removed "The patient is NOT currently receiving subcutaneous (SC) allergen immunotherapy" from Recommended Authorization Criteria. Added "Concurrent use of Grastek or Oralair with subcutaneous (SC) allergen immunotherapy (e.g., allergy shots) or sublingual (SL) allergen immunotherapy" to Conditions Not Recommended for Approval.	07/26/2017
Annual Revision	No changes to criteria.	08/15/2018
DEU Revision	Updated policy to reflect Oralair indication expanded down to 5 years of age. No change to approval criteria. Criteria previously approved and continues to approve for patients ≥ 5 years of age.	12/18/2018
Selected Revision	Removed the requirement that Grastek/Oralair be prescribed by or in consultation with an allergist, immunologist, or an otolaryngologist (ear, nose and throat [ENT]) physician specialist).	01/30/2019
Early Annual Revision	No changes to criteria.	07/10/2019

TAC – Therapeutic Assessment Committee; DEU – Drug Evaluation Unit; * For a further summary of criteria changes, refer to respective TAC minutes available at: http://esidepartments/sites/Dep043/Committees/TAC/Forms/AllItems.aspx.