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Coverage Policy Number **IP0515**

Grass Pollen Sublingual Products

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Related Coverage Resources

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for the following grass pollen sublingual products:

- 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)

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Grass pollen sublingual products (Grastek, Oralair) are considered medically necessary when the following are met:

I. Grastek (Timothy grass pollen allergen extract sublingual tablets).

1. **Grass Pollen-Induced Allergic Rhinitis.** Individual meets **ALL** of the following criteria:

A. Age 5 years or older
B. Diagnosis confirmed by **ONE** of the following:
    i. 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)
    ii. 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)
C. Documentation of failure, contraindication or intolerance to **BOTH** of the following:
    i. Intranasal corticosteroid therapy
    ii. Either oral or intranasal antihistamine
D. Treatment will be initiated at least 12 weeks before the onset of grass pollen season.

When criteria are met, a maximum of 1 tablet per day will be covered.

II. **Oralair® (Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass mixed pollens allergen extract sublingual tablets)**

1. **Grass Pollen-Induced Allergic Rhinitis.** Individual meets **ALL** of the following criteria:
    A. Age 5 years or older
    B. Diagnosis confirmed by **ONE** of the following:
        i. 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)
        ii. 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)
    C. Documentation of failure, contraindication or intolerance to **BOTH** of the following:
        i. Intranasal corticosteroid therapy
        ii. Either oral or intranasal antihistamine
    D. Treatment will be initiated 4 months before the onset of grass pollen season.

When criteria are met, a maximum of 1 tablet per day will be covered.

Reauthorization Criteria

Continuation of grass pollen sublingual products (Grastek, Oralair) are considered medically necessary for grass pollen-induced allergic rhinitis when the above medical necessity criteria are met AND there is documentation of beneficial response

Authorization Duration

Initial approval duration: up to 12 months
Reauthorization approval duration: up to 12 months

Conditions Not Covered

Any other use is considered experimental, investigational or unproven, including the following (this list may not be all inclusive):

1. **Concurrent Use of Grastek or Oralair with Subcutaneous Allergen Immunotherapy or Sublingual Allergen Immunotherapy.**
    This includes allergy shots as well as 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.

Background

OVERVIEW

Grastek and Oralair are grass pollen allergen extracts 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).[1,2] 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

Pivotal trials of Grastek and Oralair included patients with grass pollen-induced allergic rhinitis with or without conjunctivitis confirmed by either a positive skin prick test to Timothy grass pollen or positive *in vitro*.[1,2]

References

1. Grastek® sublingual tablets [prescribing information]. Swindon, Wiltshire, United Kingdom: ALK-Abello A/S; September 2022.
2. Oralair® sublingual tablets [prescribing information]. Lenoir, NC: Greer; December 2022.