Allergen Immunotherapy

EOCCO POLICY

Policy Type: PA/SP Pharmacy Coverage Policy: EOCCO110

Description

The specific mechanism of action of allergen immunotherapy has not been established. It is believed that immunotherapy works by allowing the body to develop tolerance to specific allergens through manipulation of the humoral and cellular immune responses.

Specific immunotherapy (SIT) may act by inducing a switch from T-helper 2 cell response (Th2) to T-helper 1 cell (Th1) response, resulting in the production of IgG-blocking antibodies that compete with IgE antibodies for allergen binding.

Length of Authorization

- Initial: Six months
- Renewal: 12 months

Quantity Limits

Product Name	Dosage Form	Indication	Quantity Limit
grass pollen-timothy, standard (Grastek)	2800 BAU sublingual tablet	Allergic rhinitis due to Timothy grass pollen	30 tablets/30 days
mite,d.farinae-d.pteronyssinus (Odactra)	12 SQ-HDM sublingual tablet	Allergic rhinitis due to dust mite	30 tablets/30 days
		Allergy to *Dermatophagoides farinae* and *D pteronyssinus*	
gr pol-orc/sw ver/rye/kent/tim (Oralair)	100 IR Sublingual tablet	Allergic rhinitis due to one of 5 pollen extracts	30 tablets/30 days
	100 – 300 IR sublingual tablet		
	300 IR sublingual tablet		
weed pollen-short ragweed (Ragwitek)	12 Amb a 1-U sublingual tablet	Allergic rhinitis due to ragweed	30 tablets/30 days

Initial Evaluation

I. **Grastek, Odactra, Oralair, or Ragwitek** may be considered medically necessary when the following criteria below are met:
   A. Medication is prescribed by, or in consultation with, an allergist or ear, nose, and throat (ENT) specialist; **AND**
   B. **All** the following treatments have been ineffective, contraindicated, or not tolerated:
      1. Over-the-counter oral or intranasal corticosteroids (e.g. budesonide, fluticasone propionate, mometasone furoate); **AND**
      2. Over-the-counter oral or intranasal anti-histamine (e.g. diphenhydramine, loratadine, cetirizine, azelastine); **AND**
      3. Montelukast (Singulair); **AND**
   C. A diagnosis of one of the following:
      1. **Dust mite-induced allergic rhinitis**; **AND**
         i. Member is 18 years of age or older; **AND**
         ii. Confirmed in-vitro testing for *Dermatophagoides farinae* or *D. pteronyssinus* house dust mites; **OR**
         iii. Skin testing to a licensed house dust mite allergen extract; **AND**
         iv. Request is for Odactra; **OR**
      2. Grass pollen-induced allergic rhinitis due to one of the following:
         i. Timothy grass or cross-reactive pollens; **AND**
            a. Member is five years of age or older**; AND**
            b. Confirmed by positive skin or in-vitro testing for pollen specific IgE antibodies for Timothy grass or cross-reactive pollens; **AND**
            c. Request is for Grastek or Oralair; **OR**
         ii. Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass**; AND**
            a. Member is five years of age or older**; AND**
            b. Confirmed by positive skin test or in-vitro testing for pollen specific IgE antibodies for Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass, or cross-reactive pollens; **AND**
            c. Request is for Oralair; **OR**
         iii. Short ragweed pollen; **AND**
            a. Member is 5 years of age or older; **AND**
            b. Confirmed by positive skin test, or in-vitro testing for pollen specific IgE antibodies for short ragweed pollen; **AND**
            c. Request is for Ragwitek

II. Grastek, Odactra, Oralair, or Ragwitek is considered investigational when used for all other conditions, including but not limited to:
   A. Allergic asthma
   B. Atopic dermatitis
   C. Food allergy

Renewal Evaluation

I. Member has received a previous prior authorization approval for this agent through this health plan; **AND**
II. Continuance is not for a regimen initially established through samples, manufacturer coupons, or otherwise. Initial policy criteria must be met for the member to qualify for renewal evaluation through this health plan; **AND**
III. Member experienced a decrease of allergic rhinitis during previous use

Supporting Evidence

I. Allergic rhinitis (AR) is an inflammatory, IgE-mediated disease characterized by nasal congestion, rhinorrhea (nasal drainage), sneezing, and/or nasal itching. AR may be classified by the temporal pattern of exposure to a triggering allergen, such as *seasonal* (e.g., pollens), *perennial/year-round* (e.g., dust mites), or *episodic* (environmental from exposures not normally encountered in the patient's environment, e.g., visiting a home with pets); frequency of symptoms; and severity of symptoms. It is estimated that an IgE-mediated AR may affect 1 in 6 persons within the United States. The United States population is most commonly sensitized to grass pollen, dust mites, and ragweed pollen.
II. Allergen avoidance and pharmacotherapy should be considered first when treating allergic rhinitis. Symptom management with pharmacotherapy should be considered prior to initiating immunotherapy.
III. Currently there are three classes of drugs recommended as Grade A evidence per the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNSF) 2015 guidelines in treating AR: intranasal steroids, oral or intranasal antihistamines, and oral leukotriene receptor antagonist (i.e. Montelukast). The guidelines mention that short courses of oral corticosteroids are often done in severe AR cases; however, superiority to intranasal steroids has not been shown. All three of these classes are more cost effective and have shown clinical benefit to helping lessen symptoms and symptom severity, while improving patient quality of life overall in regard to lowering the impact of AR.

IV. Allergen-specific immunotherapy (SIT) involves controlled, repetitive dosing of allergen(s) in patients diagnosed with IgE-mediated AR by history and confirmation via specific allergy testing in order to increase immune tolerance to the offending allergen(s). The ultimate goal of SIT is to decrease AR symptoms. SIT is the only proven treatment for AR that has the potential to change the natural history of the disease. Sublingual immunotherapy (SLIT) was first approved in 2014 and usually has a typical duration of 3 to 5 years of efficacy.

V. Allergen immunotherapies may cause life-threatening allergic reactions such as anaphylaxis and severe laryngopharyngeal restriction. It is recommended to monitor and administer the first dose in the presence of a health care provider and to prescribe an auto-injectable epinephrine device for home administration.

VI. Patient must have a positive skin test or in vitro testing for allergen specific IgE antibodies pertaining to the allergen immunotherapy being requested.

VII. Safety and efficacy of Grastek, Ragwitek, and Oralair has not been established in patients younger than five years old.

VIII. Safety and efficacy of Odactra has not been established in patients younger than 18 years old.

Investigational or Not Medically Necessary Uses

I. There is limited data to show safety and efficacy for all other indications.
   A. Allergic asthma
   B. Atopic dermatitis
   C. Food allergy

References

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Policy Implementation/Update:

Action and Summary of Changes	Date
Updated Ragwitek approval through age 5. Updated supporting evidence section.	5/2021
Updated to policy format. Combined existing criteria into one policy, added age requirements to match FDA-indications.	01/2020
Edit to Allergen Immunotherapy Criteria; add Odactra information and related mapping; general edits to format and criteria to accommodate Odactra.	02/2018
Combine existing criteria to create Allergen Immunotherapy Criteria	02/2018
Effective and created date of Grastek, Oralair, and Ragwitek criteria	09/2014