Oscar Clinical Guideline: Allergen Sublingual Immunotherapy (SLIT) (PG093, Ver. 5)

Allergen Sublingual Immunotherapy (SLIT)

Summary

Allergies are often the result of a hypersensitive immune response to specific substances causing an exaggerated reaction. These allergies can develop in response to various antigens including insect bites/stings, molds, dust mites, cockroaches, or seasonal pollen. Symptoms include runny nose or congestion, watery or itchy eyes, asthma symptoms, skin rashes, and in severe cases, anaphylaxis. Most allergy cases are successfully treated with over-the-counter medications, although some may require prescriptions in the form of nasal sprays, inhalers, or oral medications to prevent and/or address symptoms. When symptoms are severe or unresponsive to prescription medication, a specialized type of treatment called allergy immunotherapy may be indicated.

Allergen immunotherapy works by slowly introducing very small amounts of the allergic substance over a prolonged period of time in a controlled environment to allow a person's immune system to become desensitized. Per practice parameters of the American Academy of Allergy, Asthma & Immunology for sublingual immunotherapy, the first dose must be medically supervised in a healthcare setting while subsequent doses can be self-administered at home. Because of the associated risks, allergy

immunotherapy should always be carried out under the close supervision of a licensed practitioner trained and experienced in prescribing and administering immunotherapy. Sublingual immunotherapy treatment options include Grastek, Odactra, Oralair, and Ragwitek.

NOTE: This policy specifically addresses sublingual immunotherapy (SLIT) for the treatment of allergic rhinitis and conjunctivitis. Other forms of allergen immunotherapy are covered[ℷ] as follows:

- Subcutaneous immunotherapy (SCIT) for respiratory and Hymenoptera venom allergies - refer to Oscar Clinical Guideline: Allergy (Allergen) Immunotherapy (CG059)
- Oral immunotherapy for peanut allergy (i.e., Palforzia) - refer to Oscar Clinical Guideline: Palforzia [Peanut (Arachis hypogaea) Allergen Powder-dnfp] (PG245)

  [ℷ]*Please consult the relevant policy for specific coverage criteria. The Plan reserves the right to modify these policies and/or create additional policies as treatment options evolve. Providers should review all applicable policies and the member's benefit plan to determine coverage.*

Definitions

"Allergen immunotherapy" is a treatment where very small amounts of an allergic substance are introduced via injection or sublingual administration to a patient with that specific allergy in order to desensitize the immune system.

"Allergy" refers to having both allergen-specific IgE and developing symptoms upon exposure to substances containing that allergen.

"Anaphylaxis" is a severe, systemic immune response (e.g., affecting more than 1 organ system) which may be characterized by flushing, trouble breathing, vomiting/diarrhea, swelling in the mouth/throat, rash, etc. It can be rapidly fatal without immediate treatment.

"Antigen" (or Allergen) refers to an offending substance that causes the allergic reaction through immune system hypersensitivity. Examples of an antigen include molds, dust mites, cockroaches, certain types of pollen, or the venom of a bee sting.

"**Compendia**" are summaries of drug information and medical evidence to support decision-making about the appropriate use of drugs and medical procedures. Examples include, but are not limited to:

1. American Hospital Formulary Service Drug Information
2. Clinical pharmacology
3. National Comprehensive Cancer Network Drugs and Biologics Compendium

4. Thomson Micromedex DrugDex
5. United States Pharmacopeia-National Formulary (USP-NF)

"Rapid Desensitization" is an allergen immunotherapy technique where the protocol is performed on a shorter time scale, whereas standard allergy immunotherapy is performed over 3-5 years.

"Sensitization" is when individuals produce IgE or immune responses to allergens verified through blood or positive skin tests but do not develop symptoms upon exposure to that substance.

"Sublingual" refers to the delivery of medication under a patient's tongue.

Medical Necessity Criteria for Initial Authorization

The Plan considers **sublingual allergy immunotherapy** medically necessary when **ALL** the following criteria are met for the applicable indication listed below:

1. The requested medication is prescribed by an allergy or immunology specialist**; *AND***
2. The member is within the appropriate age group for the requested medication formulation:
    a. For Grastek: age 5 to 65 years**; *or***
    b. For Odactra: age 12 to 65 years**; *or***
    c. For Oralair: age 5 to 65 years**; *or***
    d. For Ragwitek: age 5 to 65 years**; *AND***
3. The member has IgE mediated allergic rhinitis or conjunctivitis **AND ALL** the following criteria are met:
    a. The member has experienced **ONE** or more of the following:
        i. Asthma exacerbation specifically associated with allergic rhinitis; *or*
        ii. History of 2 or more consecutive seasons of related allergy symptoms**; *or***
        iii. Perennial allergies**; *and***
    b. The member has a documented inadequate response after an appropriate trial of **ALL** of the following, unless specifically contraindicated or poorly tolerated:
        i. Avoidance of environmental or situational antigen exposure**; *and***
        ii. **ONE** of the following nasal spray treatments:
            1. Nasal antihistamine (e.g., azelastine, olopatadine)**; *or***
            2. Nasal cromolyn (sodium cromoglycate)**; *or***
            3. Nasal ipratropium**; *and***
        iii. **ONE** formulary nasal steroid (e.g., flunisolide, fluticasone, triamcinolone)**; *and***
        iv. **ONE** of the following oral medication therapies:

1. Oral antihistamine (e.g., cetirizine, desloratadine, diphenhydramine)**; *or***
2. Oral antihistamine-decongestant (e.g., cetirizine-pseudoephedrine)**; *or***
3. Oral leukotriene receptor antagonist (e.g., montelukast)**; *and***

c. There is documented positive skin prick test or allergen-specific IgE test to the specific antigen being used for immunotherapy**; *and***

d. The condition and antigen are such that there is expected to be a therapeutic benefit for the member to the requested treatment for the specified allergen; ***AND***

4. The member does **NOT** have any of the following contraindications:
   a. Current pregnancy or breastfeeding**; *or***
   b. Concurrent use of non-cardioselective beta blockers (e.g. carvedilol, labetalol, propranolol, sotalol, timolol)**; *or***
   c. Moderate to severe asthma or any uncontrolled asthma**; *or***
   d. History of severe reaction to any form of immunotherapy**; *or***
   e. History of eosinophilic esophagitis**; *or***
   f. Comorbidities that may reduce ability to survive a severe reaction to the immunotherapy or reduce the effectiveness of epinephrine, including but not limited to:
      i. Acute or chronic compromised lung function**; *or***
      ii. Significant cardiovascular diseases (e.g., unstable angina, recent myocardial infarction, significant arrhythmia, and uncontrolled hypertension)**; *or***
   g. Active oral inflammatory condition such as ulcers or dental extractions**; *AND***
      *[**NOTE**: sublingual immunotherapy can be started once this condition resolves]*
5. The requesting provider has submitted the required clinical documentation (chart notes, laboratory reports, disease progression, previous medications tried and failed, etc) for review**; *AND***
6. The medication is being prescribed within the manufacturer's published dosing guidelines (see Table 1 below) or falls within dosing guidelines found in a compendia of current literature.

Table 1: Immunotherapy for Allergic Rhinitis Dosing Information

Formulation	Indication	Initial dose	Duration
GRASTEK (Timothy Grass Pollen Allergen Extract)	Grass pollen-induced allergic rhinitis, with or without conjunctivitis (Timothy Grass Pollen Allergen Extract)	One GRASTEK tablet daily.	Initiate treatment at least 12 weeks before the expected onset of each grass pollen season and continue treatment throughout the season. For sustained effectiveness for one grass pollen season after cessation of treatment, GRASTEK may be taken daily for three consecutive years

			(including the intervals between the grass pollen seasons).
ODACTRA (House Dust Mite Allergen Extract)	House dust mite (HDM)-induced allergic rhinitis, with or without conjunctivitis	One ODACTRA tablet daily.	n/a
ORALAIR (Sweet Vernal, Orchard, Perennial Rye, Timothy, and 7 Kentucky Blue Grass Mixed Pollens Allergen Extract)	Grass pollen-induced allergic rhinitis, with or without conjunctivitis (Sweet Vernal, Orchard, Perennial Rye, Timothy, and 7 Kentucky Blue Grass Mixed Pollens Allergen Extract)	Age 5 -17 years: Day 1- 100 IR once daily Day 2- 2x 100 IR once daily Day 3 and following- 300 IR once daily Age 18 - 65 years: 300 IR once daily	Initiate treatment 4 months before the expected onset of each grass pollen season and maintain it throughout the grass pollen season.
RAGWITEK (Short Ragweed Pollen Allergen Extract)	Short ragweed pollen-induced allergic rhinitis, with or without conjunctivitis	One RAGWITEK tablet daily.	Initiate treatment at least 12 weeks before the expected onset of ragweed pollen season and continue treatment throughout the season.

NOTE: First dose should be administered in a healthcare setting under supervision of a physician experienced with severe allergic reactions. Patients should be monitored closely for 30 minutes.

If the above prior authorization criteria are met, the requested sublingual immunotherapy will be approved for 12 months.

Medical Necessity Criteria for Reauthorization

Reauthorization for 12 months will be granted if **BOTH** of the following are met:

1. the member still meets the applicable initial criteria***; AND***
2. there is documented clinical response in chart notes meeting **ONE** of the following criteria:
    a. decrease in the amount of medication required to control symptoms**; *or***
    b. improvement in clinical symptoms and benefit from treatment is sustained.

Experimental or Investigational / Not Medically Necessary

Sublingual allergen immunotherapy for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven.

Applicable Codes

ICD-10 Codes for Clinical Indications	
Code	***Description***
H10.10	Acute atopic conjunctivitis, unspecified eye
H10.11	Acute atopic conjunctivitis, right eye
H10.12	Acute atopic conjunctivitis, left eye
H10.13	Acute atopic conjunctivitis, bilateral
H10.44	Vernal conjunctivitis
H10.45	Other chronic allergic conjunctivitis
J30.1	Allergic rhinitis due to pollen
J30.2	Other seasonal allergic rhinitis
J30.5	Allergic rhinitis due to food
J30.8	Other allergic rhinitis
J30.81	Allergic rhinitis due to animal (cat) (dog) hair and dander
J30.89	Other allergic rhinitis
J30.9	Allergic rhinitis, unspecified

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