Allergen Sublingual Immunotherapy (SLIT)

- Grastek (timothy grass pollen allergen extract)
- Odactra (house dust mite allergen extract)
- Oralair (sweet vernal, orchard, perennial rye, timothy, and 7 kentucky blue grass mixed pollens allergen extract)
- Ragwitek (short ragweed pollen allergen extract)

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, eye drops 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 (Timothy Grass Pollen Allergy Extract), Odactra (*Dermatophagoides farinae* and *Dermatophagoides pteronyssinus)*, Oralair (Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass Mixed Pollens Allergen Extract), and Ragwitek (Short Ragweed Pollen Allergen Extract).

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

- Subcutaneous immunotherapy (SCIT) for respiratory and Hymenoptera venom allergies - refer to Oscar Clinical Guideline: Allergy (Allergen) Immunotherapy (CG059)

  [≈]*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)

"Documentation" refers to written information, including but not limited to:

- Up-to-date chart notes, relevant test results, and/or relevant imaging reports to support diagnoses; or
- Prescription claims records, and/or prescription receipts to support prior trials of formulary alternatives.

"No evidence of" indicates that the reviewer has not identified any records of the specified item or condition within the submitted materials or claims history. In the absence of such evidence, the member is considered eligible. If any evidence of the item or condition is present upon review of the request, the member does not qualify.

"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.

"[s]" indicates state mandates may apply.

Clinical Indications

Medical Necessity Criteria for Clinical Review

General Medical Necessity Criteria

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. IF the request is for Grastek: age 5 to 65 years; *or*
    b. IF the request is for Odactra: age 5 to 65 years; *or*
    c. IF the request is for Oralair: age 5 to 65 years; *or*
    d. IF the request is for Ragwitek: age 5 to 65 years; *AND*
3. The member has access to epinephrine (via auto-injector or nasal spray); *AND*
4. The member meets **ALL** of the following:
    a. No evidence of severe, unstable or uncontrolled asthma; *and*
    b. No evidence of history of severe allergic reaction or any severe local reaction to sublingual allergen immunotherapy; *and*
    c. No evidence of history of eosinophilic esophagitis; *AND*
5. Sublingual allergy immunotherapy is being prescribed at a dose and frequency that is within FDA approved labeling (see Appendix A, Table 2) **OR** is supported by compendia or evidence-based published dosing guidelines for the requested indication*; AND*
6. The member meets the applicable Medical Necessity Criteria for Initial Clinical Review or Subsequent Clinical Review listed below.

Medical Necessity Criteria for Initial Clinical Review

Initial Indication-Specific Criteria

IgE Mediated Allergic Rhinitis and/or Conjunctivitis

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

7. The member meets the above General Medical Necessity Criteria; *AND*
8. The member has IgE mediated allergic rhinitis and/or conjunctivitis.
9. The member has experienced **ONE (1)**of the following:
    a. Asthma exacerbation specifically associated with allergic rhinitis; *or*
    b. History of 2 or more consecutive seasons of related allergy symptoms; *or*
    c. Perennial allergies; *AND*
10. The member has a documented inadequate response after an appropriate trial of **ALL** of the following[s], unless specifically contraindicated or poorly tolerated:
    a. Avoidance of environmental or situational antigen exposure when practical; *and*
    b. **ONE (1)** of the following nasal spray treatments:

i. Nasal antihistamine (e.g., azelastine, olopatadine); *or*
ii. Nasal cromolyn (sodium cromoglycate); *or*
iii. Nasal ipratropium; *and*

c. ONE (1) formulary nasal steroid (e.g., flunisolide, fluticasone, triamcinolone); *and*
d. ONE (1) of the following oral medication therapies:
i. Oral antihistamine (e.g., cetirizine, desloratadine, diphenhydramine); *or*
ii. Oral antihistamine-decongestant (e.g., cetirizine-pseudoephedrine); *or*
iii. Oral leukotriene receptor antagonist (e.g., montelukast); *AND*

11. There is documented positive skin prick test or allergen-specific IgE test (i.e., in vitro) to the specific antigen being used for immunotherapy; *AND*
12. 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.

If the above prior authorization criteria are met, the requested product will be approved for up to 12 months.[s]

Continued Care

Medical Necessity Criteria for Subsequent Clinical Review

Subsequent Indication-Specific Criteria

IgE Mediated Allergic Rhinitis and/or Conjunctivitis

The Plan considers **sublingual allergy immunotherapy** medically necessary when **ALL** of the following criteria are met:

1. The member meets the above applicable General Medical Necessity Criteria and/or Initial Clinical Review; *AND*
2. There is documented clinical response in chart notes meeting **ONE (1)** of the following:
a. Decrease in the amount of rescue medication required to control symptoms; *or*
b. Improvement in clinical symptoms and benefit from treatment is sustained.

If the above reauthorization criteria are met, the requested product will be authorized for up to 12-months.[s]

Experimental / Investigational, or unproven[s]

Sublingual allergen immunotherapy for any other indication is considered experimental, investigational, or unproven.

Applicable Billing Codes

Table 1	
ICD-10 diagnosis codes considered medically necessary if criteria are met:	
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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Appendix A

Table 2: Immunotherapy for Allergic Rhinitis Dosing Information

Formulation	Indication	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/An/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.

Clinical Guideline Revision / History Information

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