

UNDERSTANDING ALLERGY IMMUNOTHERAPY



Provide Allergy Patients Another Option for Relief

How many of your patients suffer from allergies?

ALLERGIES ARE A BURDENSOME CONDITION FOR MANY PEOPLE IN THE US.

In fact, allergies affect nearly **50 MILLION** people throughout the United States.¹

What Is Allergy Immunotherapy?

Allergy immunotherapy (AIT), along with allergen avoidance and symptomatic pharmacotherapy, is considered a useful treatment modality in the management of allergic conditions.²

By providing AIT at your practice, you can offer patients another proven treatment option that may lead to relief of allergy symptoms.³



Complete avoidance

For most patients, although advisable, avoidance of the allergic trigger may be impossible.⁴



Symptomatic pharmacotherapy

Pharmacotherapy options can offer effective, though temporary, allergy symptom relief.⁵



Allergy immunotherapy (AIT)

Research suggests that AIT may provide modulation of the immune system.^{2,6,7}

Patients are administered gradually increasing doses of symptom-causing allergen(s) to train the immune system to reduce the allergic response when exposed to the trigger allergen(s).⁶

How Does AIT Work?

AIT is a long-term treatment for allergies²

Researchers believe that over time, allergy immunotherapy helps the patient's immune system develop resistance to allergens and reduces their ability to cause allergic symptoms.^{2,8,9}

It is believed that the incremental increases of the allergen(s) given to the patient causes¹⁰

- ✔ **The immune system to become more tolerant to the allergens**
- ✔ **A reduction in allergy symptoms when the patient is exposed to the allergens in the future**

Although the precise mechanism of action of AIT is unknown, research suggests there is the potential for long-term sustained relief of allergy symptoms. Randomized, double-blind, placebo-controlled trials demonstrate efficacy of AIT for up to 3 years.^{2,11-16}

**AIT is a
long-term
treatment for
allergies.²**



Is AIT Right for Your Allergy Patients?

Allergy Immunotherapy is appropriate when an allergy is established and the patient cannot avoid exposure to the allergen. Allergenic extracts are approved for use in allergy immunotherapy for allergic rhinitis, conjunctivitis and allergic asthma. Please see product specific packaged inserts for complete indications.^{15,17,18}

Treatment with allergenic extracts has been shown to reduce allergic symptoms of a perennial or seasonal nature such as^{15,17-21}

Rhinitis



Conjunctivitis



Immediate Hypersensitivity



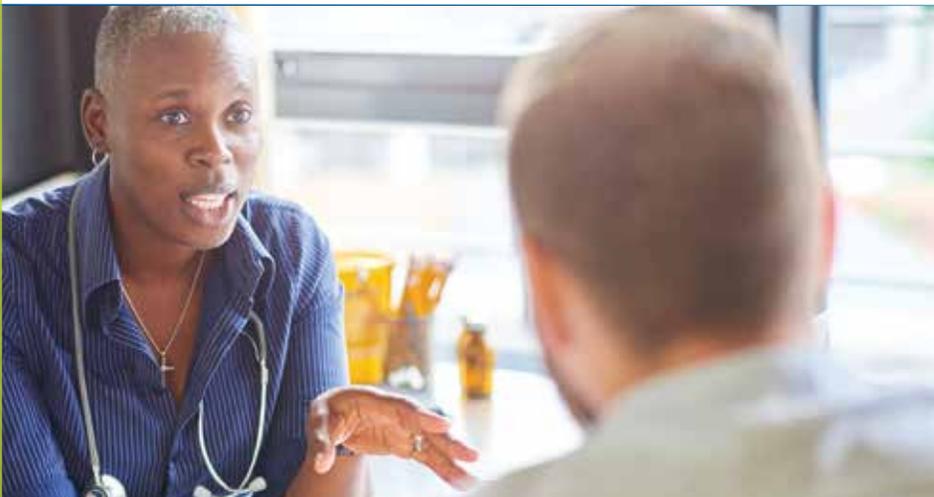
Additionally, across multiple randomized trials and meta-analyses, AIT has been shown to^{7,18,22-25}



Help Control Symptoms



Help Reduce the Need for Other Medications



What Safety Information Should I Know About AIT?

AIT has an established safety profile in children and adults.^{5,7,26,27}

The administration of AIT has been associated with severe, life-threatening systemic reactions, including anaphylaxis and death.^{15,28,29}

Some common systemic reactions of AIT include pruritus, nausea, vomiting, and urticaria.

Other reactions are dependent on the route of administration, either subcutaneous or sublingual, the most common of which are listed below.^{15,17-21,28,29}

Subcutaneous Immunotherapy

Sublingual Immunotherapy

Local reactions



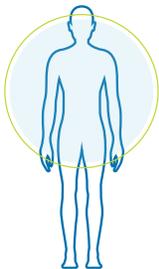
Injection site reactions:

- generalized erythema
- itching
- swelling
- tenderness
- pain

Reactions of the oral cavity:

- oral pruritus
- throat irritation
- ear pruritus
- mouth edema
- tongue pruritus
- cough
- oropharyngeal pain
- oral paresthesia
- swollen tongue

Systemic/Severe reactions



- rhinitis
- asthma
- laryngeal edema
- wheezing
- hypotension
- angioedema
- chest tightness
- syncope
- shock
- loss of consciousness
- death

- severe hypersensitivity
- severe laryngeal edema
- violent coughing
- marked dyspnea
- dysphagia
- pharyngeal edema

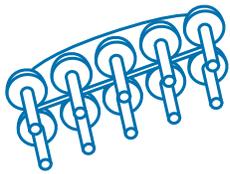
Always refer to the package insert of the particular AIT product for applicable contraindications, drug interactions, and other important safety considerations.

What Allergy Testing Options Are Available?

Patients should always be diagnosed before administering AIT. A definitive diagnosis of allergies depends on the results of allergy testing—the allergy must be confirmed with either skin or blood (*in vitro*) testing.⁷

Skin Tests

Skin tests are usually placed on the forearm or back³⁰



Prick/puncture skin test

One drop of diluted allergen is placed on the skin, and pricked or punctured into the skin²⁷



Blood (*In Vitro*) Test

- *In vitro* test: a small volume of blood is tested for a number of allergens and produces quantitative results for all test allergens²⁷
- The test measures circulating immunoglobulin E (IgE) antibodies produced against substances that individuals inhale, ingest, or with which they come in contact^{31,32}



***In vitro* allergy testing may be a good option for patients who^{31,32}**

- Are extremely sensitive to multiple skin pricks
- Have dermatographism
- Are unable to discontinue antihistamines, which may affect the results of skin testing
- Have a history of anaphylaxis or systemic reactions to allergens

You should not move forward with AIT treatment after testing in patients with⁷

- Negative test results
- Positive test results that do not correlate with suspected triggers, clinical symptoms, or exposure

What Allergy Immunotherapy Treatment Options Are Available?

You can determine the appropriate allergy immunotherapy option with which to treat your patient based on^{7,33}

- The patient's **clinical history**
- Knowledge of possible **environmental exposures**
- The results of tests for specific **IgE antibodies**
- A careful consideration of the patient's **treatment preference**

Subcutaneous AIT, also known as an allergy shot, is the most common form of AIT³⁴

Allergy shots, or injections, are given in increasing doses of an allergen mixture, customized for the patient, composed of the relevant allergen(s) to which the patient is sensitized.³⁴



The injection is administered in the office

where acute allergic reactions can be diagnosed and treated³⁵

Patients are observed for 30 minutes

for signs of severe systemic or severe allergic reaction³⁵

The most common schedule is for increasing doses administered 1 to 3 times a week,

with a maintenance dose reached within 3 to 6 months. Use your clinical judgment to determine the right treatment regimen⁷

Sublingual AIT tablet is another treatment option

The patient places a tablet that contains a small dose of the relevant allergen(s) to which they are sensitized to under the tongue.^{12,34}



The first sublingual dose is taken in the office

where acute allergic reactions can be diagnosed and treated¹³



Patients are observed for 30 minutes

for signs of severe systemic or severe allergic reaction¹³



Subsequent sublingual doses may be taken at home

if the patient tolerates the first dose³⁶



THERE ARE
FDA
APPROVED

Allergy Immunotherapy Tablets

for grass and ragweed allergies that dissolve under the tongue and are taken at home.

Consider AIT for Patients³⁷

- With **confirmed IgE-mediated disease** (symptoms on exposure to relevant allergen supported by a positive test to that allergen)
- Who are **not satisfied** with drug treatments
- Who are **unable to avoid allergens**

For whichever treatment option you and your patient decide is appropriate, remember to **give clear guidance about**³⁶

AVOIDING
treatment
interruptions

MANAGING
adverse
reactions

WHEN
to consult a
physician

Who May Benefit From AIT?



Appropriate AIT patients may be dissatisfied with **symptomatic pharmacotherapy.**⁷

Appropriate candidates for AIT are patients

- Who require high medication doses, multiple medications, or both to maintain control of their allergy⁷
- Who may be dissatisfied with symptomatic pharmacotherapy⁷
- Who want a treatment that may reduce the long-term use of symptomatic pharmacotherapy⁷
- Who are unable to avoid confirmed allergens⁷

Patients who are not appropriate candidates are those

- With severe, unstable, or uncontrolled asthma⁷
- Who are receiving treatment for cardiovascular disease⁷
- Who may be at high risk for (serious) systemic reactions⁷

Always refer to the package insert of the particular AIT product for applicable contraindications, drug interactions, and other important safety considerations.

Talking To Your Patients About AIT

Before prescribing AIT, talk to your patients about⁷

- 1 Benefits, risks, and costs**
- 2 Expected onset of efficacy**
- 3 Duration of treatment**
- 4 The importance of adhering to the immunotherapy schedule**



Helpful tips for discussing AIT

Active listening and **open communication** may help facilitate conversations

Using lay terminology can help patients better **understand your discussions**

During the conversation, remember to consider your patient's



Health insurance coverage



Travel time to appointments



Concurrent **health problems**



Perceived effectiveness of treatment, or perceived lack of need to continue treatment



Experience with any **adverse events due to AIT**

UNDERSTANDING ALLERGY IMMUNOTHERAPY

Do You Have Patients Who Suffer From Allergies?

By providing allergy immunotherapy at your practice, you can offer patients another treatment option that may lead to relief of allergy symptoms.²

You may have questions about allergy immunotherapy, such as

- ✔ **WHAT IS Allergy Immunotherapy?**
- ✔ **HOW DOES Allergy Immunotherapy Work?**
- ✔ **WHO MAY BENEFIT From Allergy Immunotherapy?**

The answers to these important questions, and more, can be found within this brochure.

References: 1. Asthma and Allergy Foundation of America. Allergy facts and figures. <http://www.aafa.org/page/allergy-facts.aspx>. Accessed on August 30, 2016. 2. Senna G, Ridolo E, Calderon M, Lombardi C, Canonica GW, Passalacqua G. Evidence of adherence to allergen-specific immunotherapy. *Curr Opin Allergy Clin Immunol*. 2009;9(6):544-8. 3. Bousquet J, Khaltaev N, Cruz AA, et al. Allergic Rhinitis and its Impact on Asthma (ARIA) 2008 update (in collaboration with the World Health Organization, GA(2)LEN and AllerGen). *Allergy*. 2008;63 suppl 86:8-160. 4. The University of Texas Medical Branch. Diagnosis and management of inhalant allergens. Quinn FP Jr, Ryan MW (eds). Grand Rounds Presentation, June 11, 2003. <https://www.utmb.edu/otoref/grnds/Inhalant-allergens-2003-0611/Inhalant-allergens-2003-0611.pdf>. Accessed on August 30, 2016. 5. Wu A. Immunotherapy - vaccines for allergic diseases. *J Thorac Dis*. 2012;4(2):198-202. 6. Incorvaia C, Mauro M, Ridolo E, et al. Patient's compliance with allergen immunotherapy. *Patient Prefer Adherence*. 2008;2:247-251. 7. Cox L, Nelson H, Lockey R, et al. Allergen immunotherapy: a practice parameter third update. Joint Council of Allergy, Asthma & Immunology, Palatine, IL. <https://www.aaaai.org/Aaaai/media/MediaLibrary/PDF%20Documents/Practice%20and%20Parameters/Allergen-immunotherapy-Jan-2011.pdf>. Accessed on August 30, 2016. 8. Canonica GW, Bousquet J, Casale T, et al. Sub-lingual immunotherapy: World Allergy Organization position paper 2009. *Allergy*. 2009;64 Suppl 91:1-59. 9. American Academy of Allergy, Asthma & Immunology. Statement of the American Academy of Allergy Asthma and Immunology to the House Committee on Energy and Commerce on the 21st Century Cures Initiative. <https://www.aaaai.org/Aaaai/media/MediaLibrary/PDF%20Documents/Advocacy/allergy-energy-and-commerce-21st-century-cures-comments.pdf>. Accessed on October 18, 2016. 10. American College of Allergy, Asthma, and Immunology. Allergy immunotherapy. <http://acaai.org/allergies/allergy-treatment/allergyimmunotherapy>. Accessed on August 30, 2016. 11. Durham SR, Walker SM, Varga EM, et al. Long-term clinical efficacy of grass-pollen immunotherapy. *N Engl J Med*. 1999;341(7):468-475. 12. Jutel M, Agache I, Bonini S, et al. International consensus on (ICON) allergy immunotherapy (AIT). *J Allergy Clin Immunol*. 2015;136(3):556-568. 13. Li JT, Bernstein DI, Calderon MA, et al. Sublingual grass and ragweed immunotherapy: clinical considerations—a PRACTALL consensus report. *J Allergy Clin Immunol*. 2016;137(2):369-376. 14. Giovane AL, Vardare M, Passalacqua G, et al. A three-year double-blind placebo-controlled study with specific oral immunotherapy to dermatophagoides: evidence of safety and efficacy in paediatric patients. *Clin Exp Allergy*. 1994;24(1):53-9. 15. ORALAIR® full Prescribing Information, Stallergenes SAS 2014. 16. GRASTEK® full Prescribing Information. Merck & Co, Inc. 2016. 17. Allergenic Extracts Standardized Mite Extract [prescribing information]. GREER. 2009. 18. Allergenic Extract Standardized Cat Hair [prescribing information]. GREER. 2015. 19. Allergenic Extract Prescription Set of Serial Dilutions [or Maintenance Vial[s]] [prescribing information]. GREER. 2004. 20. Allergenic Extracts Short Ragweed and G.S. Ragweed Mix [prescribing information]. GREER. 2005. 21. Allergenic Extracts Pollens, Molds, Epidermals, Insects, Dusts, Foods and Miscellaneous Inhalants [prescribing information]. GREER. 2004. 22. Abramson MJ, Puy RM, Weiner JM. Allergen immunotherapy for asthma. *Cochrane Database Syst Rev*. 2003;(4):CD001186. 23. Abramson MJ, Puy RM, Weiner JM. Is allergen immunotherapy effective in asthma?: a meta-analysis of randomized controlled trials. *Am J Respir Crit Care Med*. 1995;151(4):969-974. 24. Abramson MJ, Puy RM, Weiner JM. Immunotherapy in asthma: an updated systematic review. *Allergy*. 1999; 54(10):1022-1041. 25. Nanda, A, O'Connor M, Anada M, Dreskin SC, Zhang L, et al. Dose dependence and time course of the immunologic response to administration of standardized cat allergen extract. *J Allergy Clin Immunol*. 2004; 114(6):1339-1344. 26. Caminati M, Dama A, Schiappoli M, Senna G. Balancing efficacy against safety in sublingual immunotherapy with inhalant allergens: what is the best approach? *Expert Rev Clin Immunol*. 2013;9(10):937-947. 27. Drachenberg KJ, Urban E, Pröll S, Woroniecki SR. Sublingual specific immunotherapy for adults and children: a post-marketing surveillance study. *Allergol Immunopathol (Madr)*. 2004;32(2):76-81. 28. Allergenic Extracts Standardized Grass Pollen Extracts [prescribing information]. GREER. 2004. 29. Allergenic Extracts For Diagnostic Use Only Scratch, Prick, Puncture or Intradermal Testing [prescribing information]. GREER. 2004. 30. American College of Allergy, Asthma, and Immunology. Skin test. <http://acaai.org/allergies/treatment/allergytesting/skin-test>. Accessed on August 30, 2016. 31. Asthma and Allergy Foundation of America. Allergy diagnosis. <http://www.aafa.org/page/allergy-diagnosis.aspx>. Accessed on August 30, 2016. 32. Bernstein IL, Li JT, Bernstein DI, et al. Allergy diagnostic testing: an updated practice parameter. *Ann Allergy Asthma Immunol*. 2008;100(3 Suppl 3):S1-148. 33. Seidman MD, Gurgel RK, Lin SY, et al. Clinical practice guideline: allergic rhinitis executive summary. *Otolaryngol Head Neck Surg*. 2015;152(2):197-206. 34. Agency for Healthcare Research and Quality. Subcutaneous and sublingual immunotherapy to treat allergic rhinitis/rhinoconjunctivitis and asthma. <https://www.effectivehealthcare.ahrq.gov/ehc/products/270/1647/allergy-asthma-immunotherapy-clinician-130820.pdf>. Accessed on August 30, 2016. 35. American Academy of Allergy, Asthma & Immunology. Allergy Shots (Immunotherapy). [https://www.aaaai.org/conditions-and-treatments/treatments/allergy-shots-\(immunotherapy\)](https://www.aaaai.org/conditions-and-treatments/treatments/allergy-shots-(immunotherapy)). Accessed on August 30, 2016. 36. American Academy of Allergy, Asthma, and Immunology. Sublingual immunotherapy (SLIT). <http://acaai.org/allergies/treatment/sublingual-immunotherapy-slit>. Accessed on August 30, 2016. 37. Canonica GW, Durham SR. Allergen immunotherapy: a synopsis. World Allergy Organization, August 2004. http://www.worldallergy.org/professional/allergic_diseases_center/immunotherapy/immunotherapy-synopsis.php. Accessed on August 30, 2016.