

SLIT Protocol Summary

These guidelines describe a once-a-day, multi-allergen sublingual immunotherapy (SLIT) protocol that escalates progressively over several weeks to a therapeutic maintenance level.

SLIT's safety and efficacy have been shown in numerous studies, but no single, universal protocol has been established. Our recommendations are based on the latest research clinical and practice management experience for the ENT Allergy practice. Experienced pharmacy staff provide ongoing support for successful practice implementation and improved patient compliance.

Key Tenets

- Multiple-allergen immunotherapy recommended for poly-sensitized patients
- Brief escalation phase followed by high-dose maintenance level
- Phenol-free allergenic extracts mixed in a 50% glycerin solution
- · Once-daily dosing, year-round

Over the last ten years, multiple placebocontrolled studies have concluded that sublingual immunotherapy (SLIT) is effective for the treatment of allergic diseases and has been proven to be a safe route of administration. SLIT provokes immunologic changes similar to subcutaneous injection immunotherapy (SCIT), including changes in various biomarkers and mediators. (1,2) Patients treated with SLIT had a reduction in symptom and medication scores with no serious adverse reactions. (3)

SLIT significantly reduces the need for allergy medications, decreasing the money

spent on allergy symptom control. SLIT is a well-tolerated, cost-effective and time-efficient modality for the treatment of multiple allergic symptoms. (4)

Research studies indicate that treatment for longer than 12 months at higher doses provides consistent clinical and quality of life improvements with SLIT similar to SCIT. (5)

Multiple allergen SLIT has also shown to provide greater symptom relief than single allergen therapy. (6) Sublingually administered, highly glycerinated allergen extracts have been shown to remain present in the sublingual mucosa for 48 hours. (7) Once-daily dosing is convenient and leads to improved patient compliance over multiple-daily dosing.

Our recommended dosing protocols for inhalant SLIT were initially based on the American Academy of Otolaryngic Allergy (AAOA) consensus guidelines published in 2007. ⁽⁵⁾ We revised the protocols to take into consideration the use of a metered-dose dispenser for patient safety, ease of use and dispensing accuracy.



The escalation phase was modified to increase progressively, allowing sensitive patients to adjust to the higher concentrations with minimal side effects. Once achieved, the inhalant allergen maintenance phase continues for 2-5 years.

In our clinical experience, the majority of patients are poly-sensitized. Patient sensitivities to other regional pollens of clinical significance, such

as bermuda grass or birch, and perennial allergens such as mites, molds, or animal dander, should be included in treatment.

We recommend multiple, year-round, high-dose allergen therapy of the most clinically significant allergens, using FDA approved allergenic extracts mixed in a 50% glycerin solution. (8-11)

We prefer the use of phenol-free allergenic extracts when available. This practice improves the palatability of the allergy drops and avoids exposure to phenol, which even in very low concentrations, can be caustic to chemically sensitive individuals.

Allergen selection is based on the patient's degree of sensitivity, regional allergen prevalence, allergen cross-reactivity, home or occupational exposure, with special consideration of patient history and physical exam.

Treatment plan options include the use of symptom relieving medication, allergen avoidance or remediation, inhalant SLIT, dietary restrictions including elimination or rotation diets, and food SLIT. (12-17)

About All-American Allergy Alternatives, LLC

The company was founded in 2007 by Otolaryngologist Todd Meyer, DO, FAAOA, FAOCO to provide sublingual immunotherapy prescription services to meet the needs of practitioners and their allergic patients. Today, the company operates its compounding pharmacy in Appleton, WI servicing prescribers in many states across the US. Please visit www.allamericanallergy.com or call 877-667-4689 with guestions or comments.

Simple Steps to Prescribing Sublingual Immunotherapy

- 1 Patient arrives at appointment complaining of allergy symptoms.
- **2** Patient completes the "Patient Allergy History Form." (Template available)
- Based on medical history and exam, the patient is clinically diagnosed with allergic rhinitis.
- 4 Test the patient for allergies by using either an in-vitro (blood) or in-vivo (skin) technique.
 - a. In-Vitro Tests: (Allergen-specific IgE, total IgE)

Advantages:

- 1. No patient risk for adverse reaction
- 2. Current patient medications will not affect test results
- 3. Convenience to patient by using a simple blood draw
- 4. Ability to test patient for suspected food allergies
- 5. Helps differentiate IgE-mediated allergy from other disorders
- 6. Quantitative results

b. Recommended Patient Screening Panels:

Adults:

- 1. Total IgE
- 2. Regional inhalant allergy panel
- 3. Food panel (If clinically indicated)

Children:

- 1. Total IgE
- Allergen profile: Based on age and region (Recommendations can be provided.)
- 3. Food panel (If clinically indicated)
- 6 Review test results:
 - a. If all inhalant results are negative, consider non-allergic rhinitis, sinusitis, nasal polyps or other food allergy.
 - b. If some/all results are positive, continue to the next step.
- **6** Patient treatment options:

Consider sublingual immunotherapy in conjunction with initial pharmacotherapy and allergen avoidance.

- **1** If sublingual immunotherapy treatment is selected, then DEAL:
 - a. **Diagnose:** By using medical history and allergy testing (skin or blood), you are able to diagnose your patient's allergies and determine what allergens to include in their prescription. (Guidance is available from our Medical Director or Physician Liaison.)
 - 1. Complete the "SLIT Prescription Form: Inhalant Allergens".
 - 2. Patient completes the "Sublingual Immunotherapy Payment Form" or may call our office with credit card information.
 - 3. Fax both forms to 877-NOSHOTZ (877-667-4689) or mail them to the address listed below.
 - b. **Educate:** By using our educational materials, you are easily able to educate your patient regarding the use of prescription allergy drops.
 - c. Patient receives prescription in the mail or it may be delivered to your office. (If applicable to your state's pharmacy laws.)
 - d. <u>Administer:</u> With a follow-up appointment 2-3 weeks after the initial consultation, you are able to confirm that your patient is able to self-administer the drops. The patient should bring their first vial to their appointment, and a health-care provider should review the patient instructions with them.
 - e. **Look/Listen:** By having your patient self-administer the first dose in the office, you are able to observe for adverse reactions.



© Copyright 2007-2016 All-American Allergy Alternatives, LLC All Rights Reserved.

SLIT References

- 1. Sublingual immunotherapy for allergic rhinitis. Cochrane Database of Systematic Reviews. Radulovic S et al. Published online 16 Feb 2011.
- Sublingual Immunotherapy for the Treatment of Allergic Rhinoconjunctivitis and Asthma: A Systematic Review Sandra Y. Lin, MD; Nkiruka Erekosima, MD, MPH; Julia M. Kim, MD, MPH; Murugappan Ramanathan, MD; Catalina Suarez-Cuervo, MD; Yohalakshmi Chelladurai, MBBS; Darcy Ward, BA; Jodi B. Segal, MD, MPH JAMA. 2013;309(12):1278-1288. doi:10.1001/jama.2013.2049.
- 3. Quality of Life outcomes with Sublingual Immunotherapy. Wise SK, et al Am Journ Otolaryngology 2009; (30): 305-311.
- Sublingual Immunotherapy and quality of life. Laury AM, et al. Current Opinion in Otolaryngology & Head & Neck Surgery: 27 February 2013 epub doi: 10.1097/MOO.0b013e32835fcb22.
- 5. Efficacy comparison of multiple-antigen subcutaneous injection immunotherapy and multiple-antigen sublingual immunotherapy. Saporta D. Ear Nose Throat Journ 2007; 86 (8): 493-7.
- 6. Effects of sublingual immunotherapy for multiple or single allergens in polysensitized patients. Marogna M et al. Annals Allergy Asthma Immunol Vol 98, Mar 2007 274-280.
- 7. Emerging Concepts of Sublingual Immunotherapy for Allergy. DS Theodoropoulus, et al. Drugs of Today 2009, 45(10): 737-750.
- 8. Sublingual immunotherapy: current concepts for the U.S. practitioner. Lin, Sandra Y Int Forum Allergy Rhinol 2014: 4(S2): S55-S59.
- 9. Cox et al Immunotherapy Practice Parameter Update 2007. Journal Allergy Clinical Immunology, S39-40.
- 10. Airborne and Allergenic Pollen of North America, Walter H Lewis. Johns Hopkins University Press, 1983.
- 11. Allergy and Immunology-An Otolaryngic Approach. J Krouse, S Chadwick, B Gordon, MJ Dereberry. Lippincott Williams & Wilkins. 2002.
- 12. Trends in Allergic Conditions Among Children: United States, 1997-2011.

 Jackson KD et al. NCHS data brief, no 121. Hyattsville, MD: National Center for Health Statistics. 2013.
- 13. Food Allergies and Food Intolerance. J Brostoff, L Gamlin, Healing Arts Press, 2000.
- 14. Food Allergy. J James, W Burks, P Eigenmann. Elsevier- Saunders, 2012.
- 15. Sublingual Immunotherapy for Peanut Allergy: Clinical and immunologic evidence of desensitization. Kim EH et al JACI 2011 Mar; 127 (3):640-6.
- Sublingual immunotherapy for peanut allergy: Long-term follow-up of a randomized multicenter trial. Burks AW et al. J Allergy Clin Immunol. 2015 May;135(5):1240-8.
- 17. A structural basis for food allergy: the role of cross-reactivity. Bonds RS, Midoro-Horiuti T, Goldblum R <u>Curr Opin Allergy Clin Immunol.</u> 2008 Feb;8(1):82-6.