

# Clinical Care Statements



In response to member requests, your AAOA Board of Directors adopted its original Clinical Care Statements in 2015. To help assure these statements reflect the current practice of medicine, your Board of Directors adopted this expanded and updated compendium in 2020. These statements will continue to be distributed through the AAOA Today, our membership newsletter, and posted on our website [www.aaoallergy.org](http://www.aaoallergy.org) for easy reference for our members. Our intention is to assist otolaryngologists by sharing evidence-based summaries on recommended therapies and practices from the current medical literature. They do not attempt to define a quality of care for legal malpractice proceedings. They should not be taken as recommending for or against a particular company's products. The Clinical Care Statements are not meant for patients to use in treating themselves or making decisions about their care. Advances constantly occur in medicine, and some advances will doubtless occur faster than these Clinical Care Statements can be updated. Otolaryngologists will want to keep abreast of the most recent medical literature in deciding the best course for treating their patients.

This compendium of work was only achievable through the tireless efforts of our Clinical Care Statement Workgroup:

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## Compendium of Clinical Care Statements

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*Note: American Academy of Otolaryngic Allergy's (AAOA) Clinical Care Statements attempt to assist otolaryngic allergists by sharing summaries of recommended therapies and practices from current medical literature. They do not attempt to define a quality of care for legal malpractice proceedings. They should not be taken as recommending for or against a particular company's products. The Statements are not meant for patients to use in treating themselves or making decisions about their care. Advances constantly occur in medicine, and some advances will doubtless occur faster than these Statements can be updated. Otolaryngic allergists will want to keep abreast of the most recent medical literature in deciding the best course for treating their patients.*



# Risks Factors for Testing or Immunotherapy

The American Academy of Otolaryngic Allergy (AAOA) recognizes the importance of allergy skin testing and immunotherapy in the clinical practice of allergy. Although felt to be a safe practice in most patients, certain populations need to be given special consideration as they have been identified as being at a higher risk for complications during skin testing and immunotherapy. This is not intended to be an all-inclusive list.

### Pregnancy

Allergy immunotherapy can be continued during pregnancy. Escalation and skin testing should be avoided.

The most recent update on allergen immunotherapy states that allergen immunotherapy can be continued but is usually not initiated in the pregnant patient. Allergen immunotherapy is usually not initiated during pregnancy because of concerns about the potential for systemic reactions and the resulting adverse effects on the mother and fetus. For this reason, if the patient becomes pregnant during escalation and the dose is unlikely to be therapeutic, discontinuation of immunotherapy should be considered.<sup>1</sup>

### Asthma

Asthma should be well controlled prior to undergoing skin testing or before the initiation or continuation of immunotherapy. In asthma patients, consider evaluating lung function prior to administration of immunotherapy.

Immunotherapy is effective in the management of allergic asthma; however, uncontrolled asthma has been repeatedly identified as a high-risk factor for systemic reactions during skin testing and allergen immunotherapy.

The most recent update on allergen immunotherapy states that allergen immunotherapy in asthmatic patients should not be initiated unless the patient's asthma is

stable with pharmacotherapy. It is also recommended that allergy injections should be withheld if the patient presents with an acute asthma exacerbation. Before the administration of an allergy injection, the asthmatic patient should be evaluated for the presence of asthma symptoms. One might consider an objective measure of airway function.<sup>1,2</sup>

### Beta Blockers

The AAOA recognizes that exposure to beta-adrenergic blocking agents is a risk factor for more serious and treatment resistant anaphylaxis, making the use of beta blockers a relative contraindication to inhalant skin testing and immunotherapy.

The balance of possible risks and benefits is not the same for patients with the potential for life-threatening stinging insect reactions, who are also taking a beta-blocker. In these patients, the benefits of venom immunotherapy may outweigh any risk associated with concomitant beta-adrenergic blocker administration. The individualized risks/benefits of immunotherapy should be carefully considered in these patients.

Beta blockade can enhance mediator stimulus in the setting of IgE-mediated anaphylactic reactions. Therefore, concomitant treatment with beta-adrenergic blockers may result in more protracted and difficult-to-treat anaphylaxis. Studies investigating patients taking ophthalmic and cardio-selective beta-blockers have found unusually severe anaphylactic reactions and for this reason, the absence of increased risk in this population cannot be assumed.<sup>1,3,4,5,6</sup>

### Other Risk Factors

Other predictors of allergic reactions include prior allergic reactions, immunotherapy escalation, first treatment vial, and technical (dosing/wrong vial) error.<sup>7,8</sup>

- 1 Cox L, Nelson H, Lockey, R. Allergen immunotherapy: a practice parameter third update. *J Allergy Clin Immunol* 2011; 127(suppl): S1-55
- 2 Lockey RF, et al. Systemic Reactions and fatalities associated with allergen immunotherapy. *Ann Allergy Asthma Immunol* 2001; 87:47-55.
- 3 Hepner MJ, et al. Risk of systemic reactions in patients taking beta-blocker drugs receiving allergen immunotherapy injections. *J Allergy Clin Immunol* 1990; 86:407
- 4 Lang DM. Do beta-blockers really enhance the risk of anaphylaxis during immunotherapy? *Curr Allerg Asthma Rep* 2008; 8:37

- 5 Odeh M, Oliven A, Bassan H. Timolol eyedrop-induced fatal bronchospasm in an asthmatic patient. *J Fam Pract* 1991; 32:97-8, NR
- 6 Lieberman P, et al. The diagnosis and management of anaphylaxis practice parameter: 2010 Update. *J Allergy Clin Immunol* 2010;126(3): 477-523
- 7 Roy SR, et al. Increased frequency of large local reactions among systemic reactors during subcutaneous allergen immunotherapy. *Ann Allergy Asthma Immunol* 2007; 99:82.
- 8 Bernstein DI, et al. Twelve-year survey of fatal reactions to allergen injections and skin testing: 1990-2001. *J Allergy Clin Immunol* 2004; 113:1129

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# Medicines to Avoid Before Skin Allergy Testing



**T**he American Academy of Otolaryngic Allergy (AAOA) has developed this position statement to assist allergy providers in determining which medicines patients should avoid prior to skin testing. These medicines are known to decrease or eliminate skin reactivity causing a negative histamine control. Providers should have a thorough understanding of the classes of medicines that could interfere with allergy testing. With proper patient counseling, the goal is to yield interpretable skin results without unnecessary medicine discontinuation.

Antihistamines suppress the histamine response for a variable period of time. In general, first-generation antihistamines can be stopped for 72 hours, however, several types including Cyproheptadine (Periactin) can have active histamine suppression for up to 11 days. Second-generation antihistamines also suppress testing for a variable length of time, up to 7 days. Astelin (Azelastine) nasal spray has been shown to suppress testing for up to 48 hours.<sup>1, 2, 3, 4, 5, 6, 7</sup>

Short-term oral corticosteroids (30 mg daily for a week) do not suppress skin testing.<sup>8</sup> There is a difference of opinion about the effects of long-term or relatively high-dose steroids, i.e. greater than 20 mg of prednisone per day, on the suppression of immediate skin tests.<sup>9, 10</sup>

Topical glucocorticosteroids can block the histamine response.<sup>11, 12, 13</sup> Application of potent topical steroids have been shown to stop the histamine response for up to three weeks.<sup>14</sup>

Tricyclic antidepressants can suppress the antihistamine response from 7 to 14 days depending upon the type.<sup>15, 16</sup>

Benzodiazepines should be discontinued for 7 days before the testing and include clonazepam, diazepam, lorazepam, and midazolam.<sup>15</sup> Alprazolam has also been shown to inhibit skin testing.<sup>17</sup>

H2 blockers have the potential to suppress histamine skin reactions for up to two days and include cimetidine, ranitidine, and famotidine.<sup>18, 19</sup>

# TESTING

# 3

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- 1 Bernstein, L. et al Allergy Diagnostic Testing: an updated practice parameter. *Annals of Allergy and Asthma Immunology* 2008; 100:S18.
- 2 Long, WF, Taylor, RJ., Wagner, CJ., Leavengood, DC., Nelson, HS. Skin test suppression by antihistamines and the development of subsensitivity. *Journal of Allergy and Clinical Immunology* 1985; 76:113-7 (111).
- 3 Cook, T.J., MacQueen, DM., Wittig, H.J., Thornby, J.L., Lantos, R.L., Virtue, CM. Degree and duration of skin test suppression and side effects with antihistamines: a double blind controlled study with five antihistamines. *Journal of Allergy and Clinical Immunology* 1973; 51:7107. (111).
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- 6 Simons, FE., Simons, K.J., Clinical pharmacology of new histamine H1 receptor antagonists. *Clin Pharmacokinet.* 1999; 15:277-86. (11a).
- 7 Pearlman, DS., Grossman, J., Meltzer, EO. Histamine skin test reactivity following single and multiple doses of azelastine nasal spray in patients with seasonal allergic rhinitis. *Ann Allergy Asthma Immunol.* 2003; 91:258-62. (1b).
- 8 Slotki, Zweiman B. A controlled study of the effects of corticosteroids on immediate skin test reactivity. *Journal of Allergy and Clinical Immunology* 1974; 54:229-235.
- 9 Des Roches, A., Paradis, L., Bougeard, Y.H. et al. Long-term oral corticosteroid therapy does not alter the results of immediate skin allergy prick tests. *Journal of Allergy and Clinical Immunology* 1996; 98(3):522-7.
- 10 Olson, R. et al. Skin reactivity to codeine and histamine during prolonged corticosteroid therapy. *Journal of Allergy and Clinical Immunology* 1990; 86:153-159.
- 11 Andersson M., Pipkorn U. Inhibition of the dermal immediate allergic reaction through prolonged treatment with topical glucocorticosteroids. *J Allergy Clin Immunol* 1987;79:345.
- 12 Gradman J., Wolthers OD. Suppressive effects of topical mometasone furoate and tacrolimus on skin prick testing in children. *Pediatr Dermatol* 2008; 25:26
- 13 Pipkorn U. Hammarlund A., Enerback L. Prolonged treatment with topical glucocorticoids results in an inhibition of the allergen-induced wheal-and-flare response and a reduction in skin mast cell numbers and histamine content. *Clin Esp Allergy* 1989; 19:19.
- 14 Narasimha, S.K., Effective topical corticosteroid application frequency and histamine induced wheals. *International Journal of Dermatology* 2005; 44(5):425-427.
- 15 Shah, K.M. et al. Predicting which medicine classes interfere with allergy skin testing. *Allergy and Asthma Proceedings* 2010; 31:477-482.
- 16 Bousquet, J. et al. Practical guide to skin prick testing in allergy to aeroallergens. *Allergy* 2012; 67:18-24.
- 17 Duenas-Laita, A. et al. Successful treatment of chronic drug-resistant urticaria without alprazolam. *Journal of Allergy and Clinical Immunology* 2009; 123:504-505.
- 18 Kupczyk M., Kuprys I., Bochenska-Marciniak M., et al. Ranitidine (150 mg daily) inhibits wheal, flare, and itching reactions in skin-prick tests. *Allergy Asthma Proc* 2007; 28:711.
- 19 Miller, J. et al. Suppression of immediate skin tests by ranitidine. *Journal of Allergy and Clinical Immunology* 1989; 84:895-899.

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# Medicines to Avoid Before Skin Allergy Testing *(continued)*

## TESTING

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Beta blockers are a risk factor for more serious and treatment resistant anaphylaxis, making the use of beta blockers a relative contraindication to inhalant skin testing.

Treatment with omalizumab (anti-IgE antibody) can suppress skin reactivity for up to six months.<sup>20, 21</sup> No data exists for other biologic agents.

Topical calcineurin inhibitors have a variable affect. Pimecrolimus<sup>22</sup> did not affect histamine testing but tacrolimus<sup>12</sup> did.

Herbal products have the potential to affect skin prick testing. In the most comprehensive study,<sup>23</sup> using a single dose crossover study, it was felt that common herbal products did not significantly affect the histamine skin response. However, complementary and other alternative medicines do sometimes have a significant histamine response<sup>24</sup> and included butterbur, stinging nettle, citrus unshiu powder, lycopus lucidus, Spirulina, cellulose powder, traditional Chinese medicine, Indian ayurvedic medicine.

Leukotriene receptor antagonist did not affect skin testing.<sup>25, 26, 27</sup>

Selective serotonin reuptake inhibitors (SSRIs) do not affect skin testing.<sup>15, 28</sup>

Selective norepinephrine reuptake inhibitors (SNRIs) and protein pump inhibitors (PPIs) are felt not to need to be discontinued.<sup>15</sup>

Cyclosporin did not affect skin histamine response.<sup>29</sup>

ACE inhibitors did not affect skin histamine response.<sup>30</sup>

Healthcare providers should take into consideration that many of these studies are done when the patient is taking one pharmaceutical agent for a short time. It is unclear, if a patient is taking multiple pharmaceutical/herbal agents that alone have a minor effect, whether the combination of these drugs could suppress the histamine response. Therefore, it is imperative that the provider have a positive skin histamine response before proceeding with diagnostic skin testing.

This is not a comprehensive list of medications that might affect skin testing. Physicians are expected to use their clinical judgment for other medications.

**20** Noga O., Hanf G., Kunkel G. Immunological and clinical changes in allergic asthmatics following treatment with omalizumab. *Int Arch Allergy Immunol* 2003; 131:46.

**21** Corren J., Shapiro G., Reimann J., et al. Allergen skin tests and free IgE levels during reduction and cessation of omalizumab therapy. *J Allergy Clin Immunol* 2008; 121:506.

**22** Spergel JM, Nurse N., Taylor P., PameixSpake A. Effect of topical pimecrolimus on epicutaneous skin testing. *J Allergy Clin Immunol* 2004; 114:695.

**23** More, D.R., et al. Herbal supplements and skin testing. *Allergy* 2003; 58:492-494.

**24** Mainardi, T. et al. *Journal of Allergy and Clinical Immunology* February 2009; 123(2).

**25** Hill, S.L., Krouse, J.H. The effects of montelukast on intradermal wheal and flare. *Otolaryngology Head and Neck Surgery* 2003; 129(3):199-203.

**26** Simons FE, Johnston L., Gu X., Simons KJ. Suppression of the early and late cutaneous allergic responses using fexofenadine and montelukast. *Ann Allergy Asthma Immunol* 2001; 86:44.

**27** Cudhadaroglu C., Erelel M., Kiyani E., et al. Role of Zafirlukast on skin prick test. *Allergol Immunopathol (Madr)* 2001; 29:66.

**28** Isik SR, Celikel S., Karakaya G., et al. The effects of antidepressants on the results of skin prick tests used in the diagnosis of allergic diseases. *Int Arch Allergy Immunol* 2011; 154:63.

**29** Munro CS, Higgins EM, Marks JM, et al. Cyclosporin A in atopic dermatitis: therapeutic response is dissociated from effects on allergic reactions. *Br J Dermatol* 1991; 124:43.

**30** Joint Task Force on Practice Parameters, American Academy of Allergy, Asthma and Immunology, American College of Allergy, Asthma and Immunology, Joint Council of Allergy, Asthma and Immunology. The diagnosis and management of anaphylaxis: an updated practice parameter. *J Allergy Clin Immunol* 2015; 115:341

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# Medicines to Avoid Before Skin Allergy Testing *(continued)*



## Suppressant Effects of Drugs on Immediate Skin Tests\*

Medications	Mean Days Suppressed	Max Days Suppressed
First Generation Antihistamines <sup>1</sup>	2	5
Second Generation Antihistamines	2	7
Antihistamine Nasal Sprays	0	1
Antihistamine Eye Drops	0	1
Tricyclic Antidepressants and Tranquilizers		14
Histamine2 Antihistamines (H2 Blocker)	0	2
Topical Corticosteroids		Up to 21

## Medications that DO NOT Need to be Stopped Prior to Allergy Skin Prick Testing\*

Angiotensin-Converting Enzyme (ACE) Inhibitors	Benazepril Captopril Enalapril Lisinopril Perindopril Quinapril Ramipril
Immunosuppressant	Cyclosporin
Nasal Steroid Sprays	Beclomethasone Dipropionate Nasal Budesonide Nasal Ciclesonide Nasal Fluticasone Propionate Fluticasone Furoate Nasal Mometasone Furoate Nasal Oxymetazoline Triamcinolone Acetonide
Norepinephrine Reuptake Inhibitors (SNRIs)	Duloxetine Venlafaxine
Protein Pump Inhibitors (PPIs)	Esomeprazole Lansoprazole Omeprazole Pantoprazole Rabeprazole
Serotonin Reuptake Inhibitors (SNRIs)	Citalopram Escitalopram Fluoxetine Paroxetine Sertraline

1 \*Some exceptions—see prior references

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TESTING

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# Skin Testing Techniques for Immediate and Delayed Hypersensitivity Reaction

## 6 TESTING

There are multiple techniques for allergy testing available to confirm or identify aeroallergen allergic disease as well as the level of sensitivity. These include in vivo and in vitro modalities. It is important to have a technique that is standardized with the use of appropriate controls to be reproducible, sensitive and specific.

Skin testing techniques for immediate and delayed sensitivity are an important method of testing to identify and confirm allergic disease.

**1 Percutaneous (Prick) Testing:** Prick testing utilizes a non-traumatic introducer device. Reproducible results can be obtained based on the location of testing on the body, potency of allergen extracts, and the proficiency of the skin tester.<sup>1</sup>

**2 Intradermal Testing:** single intradermal and intradermal dilutional testing techniques can give both qualitative and quantitative sensitivity information

**3 Modified Quantitative Testing (MQT or blended techniques):** is an accurate and can be a more cost-effective method of testing than intradermal dilutional testing alone, while still obtaining quantitative results.<sup>2,3</sup> MQT is one method to blend skin prick testing with intradermal testing to help assess sensitivity.

**4 Scratch Testing:** is a technique that is less sensitive, more painful, not reproducible and is not recommended for diagnostic testing.<sup>4</sup>

1 Bernstein, L. et al. Allergy Diagnostic Testing: an updated practice parameter. *Annals of Allergy, Asthma, and Immunology* 2008, Volume 100, Number 3, Supplement 3. S15-S29.

2 Krouse, JH. Skin Testing for inhalant allergy 2003: current strategies. *OTO-HNS Journal*, October 2003; 129 (4 Suppl): 33-49.

3 Council on Scientific Affairs. In vivo diagnostic testing and immunotherapy for allergy. Report I, Part I, of allergy panel. *JAMA* 1987;258(10):1363-7.

4 *Int Forum Allergy Rhinol.* 2018 Feb; 8 (2) 108-352. doi: 10.1002/alar.22073

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# In Vitro Testing / Allergen-Specific IgE



The AAOA supports the use of in vitro testing as a diagnostic option. Similar to skin testing techniques, in vitro testing aims to confirm the suspicion of IgE-mediated disease by confirming the presence of allergen-specific IgE in the allergic patient. Serologic evaluations for allergic disease include RAST, mRAST, CAP, and more recently molecular allergy/component testing. In vitro testing is especially helpful in patients who are not candidates for skin testing.<sup>1</sup>

For many clinical conditions, in vitro testing can be considered an alternative to skin testing. Compared to skin testing, in vitro testing correlation varies with individual antigens and ranges from less than 50% to greater than 90%. Negative in vitro test results, however, need to be correlated clinically as negative results may not exclude clinical disease.<sup>2</sup>

The AAOA recommends the use of in vitro testing in the following subsets of patients.

- Patients with severe or poorly controlled asthma
- Prior systemic reactions to suspected antigens
- Certain dermatologic conditions
- Use of (or inability to discontinue) medications that may mask the cutaneous response or may make anaphylaxis more difficult to treat.

Molecular allergy/component-resolved testing includes single molecular allergen/component testing, allergen specific panels covering a single allergen, or micro-array semi-quantitative testing panels.

Molecular allergy technology still requires more extensive FDA review before it can become integrated to current allergy practice standards. Its ability to distinguish true sensitization from cross-reactive sensitization in poly-sensitized patients, to better determine the risk of systemic reaction in food allergy, and to improve the indications for immunotherapy in specific clinical contexts will position its use relative to conventional serologic specific IgE testing.<sup>3</sup>

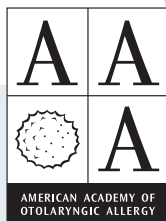
The AAOA recommends further consideration of molecular allergy as an additional diagnostic means in allergy diagnosis.<sup>3</sup>

<sup>1</sup> Bernstein, L. et al Allergy Diagnostic Testing: An updated practice parameter. *Annals of Allergy, Asthma, and Immunology* March 2008; 100:S44.

<sup>2</sup> Gabriele De Vos, MD, et al. Discordance Between Aero Allergen Specific Serum IgE and Skin Testing in Children Younger Than Four Years. *Ann Allergy, Asthma, Immunol* 110 (2013) 438-435.

<sup>3</sup> Canonica, WG, A WAO - ARIA - GA<sup>2</sup>LEN consensus document on molecular-based allergy diagnostics, *World Allergy Organization Journal* 2013, 6:17-  
<https://waojournal.biomedcentral.com/articles/10.1186/1939-4551-6-17>

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# Immunotherapy Vial Preparation — Practical Considerations

After undergoing allergy testing, either in vivo or in vitro, a patient may elect to pursue subcutaneous (SCIT) or sublingual (SLIT) allergy immunotherapy. Once prescribed, the immunotherapy vials may be formulated in physician's office, under sterile conditions according to the current USP General Chapter <797> Pharmaceutical Compounding – Sterile Preparations standards. Learn more at: <http://www.aoallergy.org/practice-2/practice-resource-tool-kit/> or at <http://www.ups.org/compounding/general-chapter-797>.

Allergy immunotherapy vials must include additives for bacteriostasis and preservation of potency. There are three available diluents and additives presently used in the preparation of immunotherapy vials used for either subcutaneous or sublingual routes. It is recommended that agents that are bacteriostatic and act as antigen stabilizers be utilized.

- Glycerin can act as both a bacteriostatic agent and an antigen stabilizer in higher concentrations.
- Phenolated saline, which is used as the main diluent in formulating immunotherapy vials, is bacteriostatic. However, when used without an additive a marked decrease in antigen potency was noted.<sup>1,2,3</sup>
- Human serum albumin (HSA) acts as a stabilizer and also decreases adherence of the antigen to glass vials.<sup>1,2,4,5,6</sup>

When preparing immunotherapy vials for sublingual therapy one should consider using 50% glycerin as the diluent, to incorporate the bacteriostatic and stabilizing properties and improve palatability.

In addition, it is recommended that allergy practitioners maintain consistency with antigen lots and antigen suppliers as much as possible to reduce variation of potency and dose.<sup>2</sup>

However, the AAOA recognizes the need to switch antigen suppliers under certain circumstances. Caution

should be used when changing lots of individual antigens, and especially when changing antigen suppliers, as potency can vary significantly, even in well-characterized or standardized extracts.

If a change in antigen supplier is necessary, options include:

- 1 Re-testing affected patient(s) with the antigens from the new antigen supplier to establish new endpoints for immunotherapy thereby establishing a new safe initial dose.
- 2 Implementing the recommendations of the antigen supplier for conversion.

In all circumstances, a new vial test is highly recommended whenever a new lot of antigen or a new antigen supplier is used.

Also, several clinical scenarios have been identified in which a single treatment vial for immunotherapy may not be adequate. It is recommended to consider separating antigens with known high proteolytic activity from antigens that are sensitive to proteases or antigens with low proteolytic activity to preserve their potency over the course of immunotherapy treatment.<sup>3,7</sup>

In addition, at least temporary separation of antigens into more than one vial may be considered when there are antigens to which a patient is highly sensitized, in order to minimize the risk of reaction, as well as, avoid hindering advancement of less sensitive antigens during escalation.<sup>3,7,8</sup> Also, separation may be necessary if the number of antigens included in the patient's vaccine exceeds what is allowable based on the total volume of the treatment vial.<sup>3,7</sup>

For further information on supervision, "incidence to," and beyond-use date (BUD), please refer to the Clinical Care Statement on *Allergen Extract Compounding of In Office Immunotherapy Vials* and the AAOA's Practice Resources Toolkit — [www.aoallergy.org/practice-2/practice-resource-tool-kit/](http://www.aoallergy.org/practice-2/practice-resource-tool-kit/)

- 1 Nelson HS. Effect of preservatives and conditions of storage on the potency of allergy extracts. *J Allergy Clin Immunol.* 67(1): 64–69, Jan 1981.
- 2 Bosquet J, Lockey R, Malling H-J. Allergen immunotherapy: Therapeutic vaccines for allergic diseases - A WHO position paper. *J Allergy Clinical Immunology.* 102(4):558-62. Oct 1998.
- 3 King HC, et al. Allergy in ENT Practice, second edition. *Theme Medical Publishers, Inc.* New York, NY, 2005: 226-229, 273-79
- 4 Cox L, et al. Allergen Immunotherapy: A practice parameter third update. *J Allergy Clin Immunol.* 27(1):S1-S55. 2010.

- 5 Nelson HS, et al. Studies of allergen extract stability: The effects of dilution and mixing. *J Allergy Clin Immunol.* 98(2): 382-388, Aug 1996.

- 6 Gilbert KC, et al. Antibacterial properties of additives used in injection immunotherapy. *International Forum Allergy Rhinology,* 2(2): 135-8, Mar-Apr 2012.

- 7 Haydon RC III, Gordon BR. Aeroallergen immunotherapy. In: Krause HF, et al., ed. *Allergy and immunology: an otolaryngic approach.* Philadelphia, PA: *Lippincott Williams & Wilkins,* 2002;170-1.

- 8 Ward WA Jr. Skin endpoint immunotherapy. In: Krause HF, ed. *Otolaryngic allergy and immunology.* Philadelphia, PA: WB Saunders, 1989: 155-62

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# Subcutaneous Immunotherapy (SCIT) for Aeroallergen Immunotherapy



IMMUNOTHERAPY



American Academy of Otolaryngic Allergy | Clinical Care Statements | August 2020

Allergic disease is a prevalent problem that affects approximately 20-25% of the population.<sup>1,2</sup> Diagnosis of this disease process is based on clinical evaluation and quantitative in vitro or in vivo testing necessary before initiating immunotherapy.<sup>3</sup> In addition to allergen avoidance and pharmacotherapy, additional treatment options include subcutaneous immunotherapy. This option has been shown to be effective in multiple randomized controlled trials in patients with allergic disease.<sup>2,4</sup> Clinically relevant allergen identification and documentation of IgE-mediated disease is necessary prior to starting subcutaneous immunotherapy. Consideration for immunotherapy is based on the severity and duration of disease, and response to or tolerance to medical therapy.<sup>2</sup>

Additionally, the level of sensitivity will determine the starting dose for safe and effective therapy.<sup>5</sup>

Individual results may vary; however, on average, duration of therapy is usually 3-5 years for adequate immunologic response.<sup>6,7,8,9</sup> A physician or provider must evaluate patients periodically during therapy, to determine safety and efficacy, monitor adverse reactions, and to make appropriate adjustment to therapy, especially during the escalation phase. It is important to note that the 30-minute wait does not reduce the risk of anaphylaxis, but allows the reaction to be observed and appropriately treated. Though extremely rare, the risks for serious potentially life-threatening responses exist.<sup>10</sup> Patients need to be counseled on the potential risks and benefits of immunotherapy with informed consent.<sup>11</sup>

- 1 Airborne Allergens: Something in the Air. NIH Publication No. 03-7045; National Institute of Allergy and Infectious Disease. US Dept of Health and Human Services; 2003.
- 2 Schiller, JS., Lucas, JW., Peregoy, JA. Summary of Health Statistics for US Adults; National Health Interview Survey 2011. National Center for Health Statistics US Dept of Health and Human Services for Disease Control and Prevention. Vital Health Stat 2012; (252); 12 207.
- 3 Krouse JH, Mabry RL. Skin Testing for Inhalant Allergy 2003; Current Strategies. Oto HNS: 129 (4) supplement: S33-49
- 4 The Journal of Allergy and Clinical Immunology, vol 102, issue 4, pp 558-62.
- 5 Gordon, BR. Immunotherapy: rationale and mechanisms. Otolaryngology Head Neck Surgery 1992; 107:861-865.

- 6 Oto-HNS 1995; 113: 597-602 <http://journals.sagepub.com/doi/full/10.1177/019459989511300511>
- 7 Allergy 1996; 51:430-433 <https://onlinelibrary.wiley.com/doi/abs/10.1111/j.1398-9995.1996.tb04643.x>
- 8 King HC, Mabry RL, et al. Allergy in ENT Practice: The Basic Guide. 2nd ed. New York, Thieme; 2005. <https://www.ncbi.nlm.nih.gov/pubmed/17521025>
- 9 Cox L, Cohn JR. Ann Allergy Asthma Immunol 2007; 98:416-426 <https://www.ncbi.nlm.nih.gov/pubmed/21122901>
- 10 Cox L et al. J Allergy Clin Immunol. 2011 Jan; 127 (Suppl): S1-55.
- 11 Hurst DS, Gordon BR et al. Safety of Home Based and Office Allergy Immunotherapy: a Multicenter prospective Study. Oto-HNS 1999; 121:553-561.

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# Sublingual Immunotherapy (SLIT)

**S**ublingual immunotherapy (SLIT) is a validated, safe, and effective form of immunotherapy in adults and children.<sup>1,2,3,4</sup> It is widely incorporated as a therapeutic option both internationally and domestically.

Subcutaneous injection is the main route of immunotherapy delivery in the United States; however, in the last 20 years, SLIT administration has become widely adopted.<sup>2</sup> Several advantages of SLIT include safety, increased tolerance, including in children, and improved access.<sup>5</sup>

Efficacy for SLIT may vary depending on antigen selection. Single agent immunotherapy, i.e., grass pollen tablets, are shown to be effective.<sup>6</sup> In multi-sensitized

patients, additional antigens may be required for treatment optimization. Dosing algorithms are in use and optimal dosing continues to be evaluated.

The FDA has granted approval for grass, ragweed, and dust mite antigens. Both sublingual drops and tablets should be provided with an understanding of potential for anaphylaxis and the patient should be instructed and educated appropriately.

Note: SLIT is typically not covered by insurance and an out-of-pocket service. It is not considered parenteral delivery and does not fall within the scope of SCIT immunotherapy codes. Some payers specifically state sublingual therapy is not covered.

- 1 Radulovic S, Calderon MA, Wilson D, Durham S. Sublingual immunotherapy for allergic rhinitis. Cochrane Database of Systematic Reviews 2010, Issue 12. Art. No.: CD002893. DOI: 10.1002/14651858.CD002893.pub2.
- 2 Lin, SY et al. Sublingual Immunotherapy for the Treatment of Allergic Rhinconjunctivitis and Asthma: A Systematic Review. JAMA 2013; Vol 309, No. 12 pp 1278-1288.
- 3 Kim, J, et al. Allergen-Specific Immunotherapy for Pediatric Asthma and Rhinoconjunctivitis: A Systematic Review. Pediatrics. Vol. 131. No. 6 June 1, 2013. pp 1155-1167

- 4 Cox, L, et al. Allergen immunotherapy: A practice parameter third update. J Allergy Clin Immunol. 2011 Mar; 127 (3): 840.
- 5 Leatherman, BD et al. Sublingual Immunotherapy: Past, Present, Paradigm for the Future. A review of the literature. Oto-HNS. Volume 136: 3, Supplement, March 2007.
- 6 Senna, GE, Calderon, M. and Milani, M. Allergy immunotherapy tablet: Graza for the treatment of grass pollen allergy. Expert Rev Clin Immunol. 2011 Jan; 7 (1): 21-7.

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# Vial Testing



The American Academy of Otolaryngic Allergy (AAOA) recommends that vial testing be performed on every patient prior to the initiation of subcutaneous allergy immunotherapy. We recommend vial testing be done on every new treatment vial to catch potential issues related to increased potency of new vials, mixing errors or lot changes of antigen, new or different agent supplier, testing for an antigen not previously introduced, and an increased antigen concentration. Vial testing is to maintain safety for the delivery of immunotherapy and is not a billable procedure. The National Correct Coding Initiative (NCCI) explains vial testing as follows<sup>1</sup>:

*“Physicians should not report allergy testing CPT codes for allergen potency (safety) testing prior to administration of immunotherapy. Confirmation of the appropriate potency of an allergen vial for immunotherapy administration is an inherent component of immunotherapy.”*

The vial test will improve the safety and may improve comfort of subcutaneous allergy immunotherapy. Vial testing serves as a biologic indicator of tolerance to the mixed antigen vial.<sup>2</sup> A large skin wheal after an intrader-

mal vial test may indicate the antigen concentration is too high for the patient. Although there is a paucity of data on this issue, a large local skin reaction may identify those that may be at a higher risk for developing a systemic reaction. In addition, a large response may result in pain and discomfort of immunotherapy injections that, if continued, may result in patient noncompliance to therapy.

Vial testing is the process of applying a much smaller dose (typically 5-fold less) of the treatment vial intradermally to assess for a skin wheal. Typically, a 4-mm wheal is applied as an intradermal injection. If after 10 minutes, the wheal size is 13 mm or less, then the first subcutaneous injection may be given during this visit. If the size is 13 mm in size, then the injection should be given on the next visit. If the size is greater than 13 mm, then the treatment vial needs to be diluted 5-fold and another vial test performed in a week.<sup>3</sup>

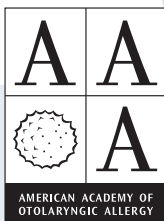
Persistently large wheals may indicate an error in the mixing of the treatment vial as noted above, or even a higher prevalence of the offending antigen in the environment. If large wheals persist after dilution, further dilution or selective retesting may be performed.

<sup>1</sup> NCCI Policy Manual, Chapter 11, Section K, 4

<sup>2</sup> Krouse, JH, Chadwick, SJ, Gordon, BR, Derebery, MJ. Allergy and Immunology - An Otolaryngic Approach. Lippincott 2002.

<sup>3</sup> King HC, Mabry RL, Mabry CS, Gordon BR, Marple BF. Allergy in ENT Practice: The Basic Guide. Thieme, 2004.

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### Definition

Anaphylaxis is defined as a serious allergic reaction that is rapid in onset and may cause death.<sup>1</sup>

The acute onset of a reaction (minutes to hours) with involvement of the skin, mucosal tissue or both and at least one of the following: a) respiratory compromise or b) reduction in systemic blood pressure or signs/symptoms of end-organ dysfunction.<sup>2</sup> The prevalence of anaphylaxis is estimated to be as high as 2%, and appears to be rising, particularly in the younger age group.<sup>1</sup>

### Clinical Presentation

Anaphylaxis has many different signs and symptoms and can present differently among patients. The most common manifestation of anaphylaxis is cutaneous, including urticaria and angioedema, and can occur up to 90% of the time. However, the absence of cutaneous signs does not rule out anaphylaxis.<sup>3</sup> The respiratory system is the second most common system affected, including dyspnea, bronchospasm, and wheezing. The gastrointestinal and cardiovascular systems can be affected as well causing nausea, vomiting, diarrhea, abdominal pain, hypotension.<sup>4</sup> Other less common manifestations can occur such as headache.

Signs and symptoms of anaphylaxis can appear within minutes of exposure to an allergen. Be aware that some reactions can appear greater than 30 minutes after exposure. Anaphylaxis can be biphasic meaning that symptoms can recur hours after resolution of the initial phase secondary to treatment. When this occurs, most of the time it is within 10 hours. Patients should be monitored for at least several hours after initial resolution of symptoms with consideration for overnight observation after more severe episodes (the optimal duration of the observation period has not been established in the literature).<sup>5</sup>

When discharged, patients must be counseled of these facts and strong consideration should be made to provide auto-injectable epinephrine along with instructions for use.<sup>2,3</sup>

### Management of Anaphylaxis— Immediate Intervention<sup>3</sup>

To successfully manage anaphylaxis, clinicians should not confuse anaphylaxis with vasovagal reactions, asthma, panic attack, or other entities. Clinicians must be aware that initial mild symptoms may progress rapidly into a life-threatening situation unless identified and treated promptly. Epinephrine is the only first-line treatment and any delay in administration can lead to serious consequences, including death. Treatment recommendations and decisions to transfer patients to a different care setting are made on an individual basis by the physician. Please note that the following recommendations do not have to be followed in the stepwise order presented and many of these interventions should happen simultaneously.

- 1 Assess airway, breathing, and circulation. Monitor vital signs.
- 2 Administer epinephrine  
Aqueous epinephrine 1:1000 dilution (1 mg/ml): 0.2-0.5 ml IM in lateral thigh or subcutaneously every 5 min as necessary to control symptoms. In children, 0.01 mg/kg, max 0.3 mg dosage.
- 3 Call 911.
- 4 Place patient in supine position with lower extremities elevated.
- 5 Administer oxygen.
- 6 Obtain IV access and administer rapid IV fluid replacement.

1 Kim H, Fischer D. Anaphylaxis. All Asth Clin Immun 7, S6 (2011) doi:10.1186/1710-1492-7-S1-S6.

2 Tang A. A Practical Guide to Anaphylaxis. Am Fam Physician 2003; 68:1325-32

3 Lieberman P. The risk and management of anaphylaxis in the setting of immunotherapy. Am J Rhinol Allergy 26, 469-474, 2012.

4 Hurst DS, Gordon BR, et al. Safety of Home Based and Office Allergy Immunotherapy: a multicenter prospective study. Otolaryngol Head and Neck Surg 1999; 121:553-561

5 Lieberman P. Recognition and First-line Treatment of Anaphylaxis. Am J Med. 2014 Jan; 127(1 Suppl):S6-11.

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- 7 Place tourniquet above injection site.
- 8 Consider diphenhydramine 1-2 mg/kg or 25-50 mg/dose parenterally.  
NOTE: H1 antihistamines are second-line and should not be administered instead of epinephrine in the treatment of anaphylaxis.
- 9 Consider H2 blockers as a second-line treatment that should not be administered instead of epinephrine.
- 10 Consider inhaled beta-agonist (MDI or nebulized) for bronchospasm.
- 11 Consider IV/IM steroids. NOTE: steroids do not work acutely and should not be used in place of epinephrine.
- 12 Consider advanced cardiac life support measures for cardiopulmonary arrest during anaphylaxis.
- 13 Endotracheal intubation or a surgical airway may be needed if respiratory distress persists or worsens after initial treatment.
- 14 Consider glucagon in patients taking beta-blockers with refractory symptoms. The recommended dose is 1-5 mg administered IV over 5 minutes followed by a 5-15 ug/min infusion that can be titrated. In children, the dose is 20-30 ug/kg with a maximum dose of 1 mg.

## Prevention

Clinicians should recognize that there are certain factors that could potentially put patients at increased risk of anaphylaxis. These include active asthma, immunotherapy escalation, vial prepared in another office, errors in dosing, injection of wrong patient serum, immunotherapy injections during peak allergy season, first injection from a new vial, and history of anaphylaxis.<sup>6</sup>

It remains controversial if preceding large local reactions predict systemic reactions.<sup>5</sup>

Underlying medical conditions must be taken into consideration if treatment of anaphylaxis may pose a significant health risk (e.g. administration of epinephrine in patients with cardiovascular disease).

Medications prescribed for common medical conditions can also place patients at increased risk. Beta-blocker therapy may render a patient more refractory to management with epinephrine. ACE inhibitors have been shown to increase risk of anaphylaxis in those undergoing venom immunotherapy.<sup>6</sup>

## Patient Education

Patients undergoing immunotherapy and those with a history of anaphylaxis should be instructed on how to recognize signs and symptoms of anaphylaxis. They should also be instructed on how to properly administer auto-injectable epinephrine. Family members (particularly of children) should be educated on recognition and initial treatment of anaphylaxis with epinephrine. Education specifically on use of auto-injectable epinephrine is recommended.

## Preparation

Offices and facilities administering immunotherapy should be prepared to treat anaphylaxis. Physicians and office staff should have an established protocol in place, which can be reinforced with rehearsal drills.<sup>6,7</sup>

Anaphylaxis treatment medications should be immediately available and replaced if used or expired. Health providers administering injections should be trained in the recognition and management of anaphylaxis. It is recommended to continually review medications, which patients take, prior to administration of immunotherapy to avoid placing patients at higher risk of a systemic reaction.

6 Simons, F.E.R., Ebisawa, M., Sanchez-Borges, M. et al. 2015 update of the evidence base: World Allergy Organization anaphylaxis guidelines. *World Allergy Organ J* 8, 1-16 (2015). <http://www.worldallergy.org/anaphylaxis>

7 Leatherman BD. Anaphylaxis in the allergy practice. *Int Forum Allergy Rhinol.* 2014;4:S60-S65.



# Anaphylaxis Crash Cart Supplies

The American Academy of Otolaryngic Allergy (AAOA) has developed this clinical care statement to assist healthcare providers and their practices to identify supplies to help manage anaphylaxis.

Supplies for anaphylaxis should be organized in such a way that they are readily accessible and can be easily moved to the patient experiencing anaphylaxis.

The crash cart should be regularly checked to ensure that all the medications are not past their expiration date.

In addition to having a crash cart readily available, physicians and nursing staff should collaborate to develop a customized written protocol for the management of

anaphylaxis in the office. Once developed, it should be posted in all patient areas of the office with the emergency supplies for ready access.

Regular, organized, mock anaphylaxis drills in which all staff members, clerical and medical, are required to participate can help ensure preparedness for these events.

Maintaining clinical proficiency with anaphylaxis management involves certification in basic cardiopulmonary resuscitation and, ideally, advanced life support to ensure the proper skill set for treatment of refractory anaphylaxis, including airway management, cardiac compressions, venous access, and parenteral medication calculation and delivery.

## Basic Medications and Dosing for Office Management of Anaphylaxis

### Epinephrine

Adult dosing

0.3–0.5 mg IM (0.3–0.5 mL of a 1:1000 solution)

May repeat every 5–10 minutes

Pediatric Dosing

0.01–0.03 mg/kg IM (0.1–0.3 mL/kg of 1:1000 solution)

May repeat at 15-minute intervals

### Albuterol

Adult: metered dose inhaler: 2–4 puffs

Pediatric: (nebulizer) 0.25–0.5 mL in 1.5–2 mL saline

### Diphenhydramine

Adult: 100 mg IV push

Pediatric: 1 mg/kg IV push

### H2 Blockers

Adult: 50 mg slow IV push

Pediatric: 2 mg/kg (up to 50 mg) slow IV push

### Dexamethasone

Adult: 20 mg IV or PO

Children: 0.5–1 mg/kg up to 20 mg IV

### Methylprednisolone

Adult: 40 mg IV

Pediatric: 0.5 mg/kg IV

IM = intramuscular; IV = intravenous; PO = by mouth (per os).

1 Leatherman BD. Anaphylaxis in the allergy practice. *Int Forum Allergy Rhinol*. 2014;4:S60–S65.

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# Allergen Extract Compounding of In-Office Immunotherapy Vials



### Background

Allergy diagnosis and management includes the need for physicians to prepare the immunotherapy prescription sets in their office. This preparation falls within the US Pharmacopoeia (USP) definition of sterile compounding. Physicians with training and expertise in allergen immunotherapy are qualified to safely compound allergy immunotherapy vials in their own office, if specific criteria are met. These criteria are defined by the USP and fall under USP General Chapter <797> Pharmaceutical Compounding — Sterile Preparation.

The American Academy of Otolaryngic Allergy (AAOA) working in concert with its allergy cohort and other impacted medical specialties worked closely to help assure allergen immunotherapy compounding was not compromised in the updated guidance.

In addition to adherence to USP General Chapter <797>, FDA guidance on sterile compounding also applies to the preparation of allergy immunotherapy.

Ultimately, each office needs a standard operating procedure (SOP) that outlines its formal mixing standards and procedures. Within this SOP, documentation regarding training, personnel qualifications, prescription mixing logs, allergenic extract supply logs, temperature logs, physician supervision, and related details to meet both the practice's SOP and USP General Chapter <797> guidance should be maintained.

The compounding bill, passed by Congress in November 2013, enforces regulation of compounding pharmacies. The statute contains two provisions that impact allergy immunotherapy:

- All compound sterile preparations must have a prescription
- Physicians must comply with all of the USP General Chapter <797> Pharmaceutical Compounding — Sterile Preparation criteria <sup>1</sup>

Like allergy testing, allergy immunotherapy compounding falls under both “Direct Supervision” and “Incident to” rules. Compliance with direct supervision and “incident to” requirements apply to in-office allergen extract compounding for allergen prescription set vial preparation. Code 95165 & 95144 describe the supervision and provision of antigens for allergy immunotherapy, whether single or multiple antigens.

- CPT codes are assigned a level of supervision:
  - **General:** Physician does not need to be on premise, but have management responsibility for staff who does the test
  - **Direct:** Physician needs to be in the office suite, but does not need to be in the room when the test is done.
  - **Personal:** Physician needs to be in the room when the test is performed
- Supervision for preparation of immunotherapy falls under **direct supervision** — meaning the physician needs to be in the office suite, but does not need to be in the room.
- Immunotherapy services are **“incident to”**, requiring direct supervision within the office suite
- “Incident to” also confirms that this service must be done in the physician’s office under the physician’s supervision; If you **outsource** compounding you **cannot bill** codes 95165 or 95144.

Rules defining scope of practice for APPs vary by state. We recommend consulting with your state medical society for a better understanding of how supervision and incident to apply to AAPs in your state. For more on scope of practice, please review the AAOA Clinical Care Statement on State Regulations.

<sup>1</sup> Lin, SY et al. Impact of newly revised sterile medication compounding guidelines USP <797> on allergy vial prep. Otolaryngology-Head and Neck Surgery (2008): 139, 5-6.

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# Allergen Extract Compounding of In-Office Immunotherapy Vials

## USP General Chapter <797> Compliance

### USP General Chapter <797> Pharmaceutical Compounding – Sterile Preparations – 2019 Update Details

Under the new standards, in-office compounding of individual treatment sets for allergen immunotherapy, beginning Dec. 1, 2019 (**currently postponed until further notice**), need to comply with the following:

#### Personnel Qualifications

- Designate one person with training and expertise in allergen immunotherapy to ensure all personnel who will be preparing allergen immunotherapy are trained, evaluated, and supervised.
- All personnel must complete training and be able to demonstrate knowledge of principles and skills for sterile compounding
- Annual personnel training and competency must be documented.
- Personnel must demonstrate proficiency in sterile compounding procedures by passing written or electronic testing before they can be allowed to compound allergenic extract prescription sets.
- All compounders must successfully complete gloved fingertip and thumb sampling on both hands, no fewer than 3 separate times. Each fingertip and thumb evaluation must occur after performing separate and complete hand hygiene and garbing procedure.

#### Hygiene and Garbing

- Before beginning allergen immunotherapy prescription set compounding, personnel must perform hand hygiene and garbing procedures according to facility Standard Operating Procedures (SOP).
- Minimum garb requirements:
  - o sterile, powder-free gloves;
  - o low-lint, sleeved garments that fit snugly around the wrists and enclose at the neck (e.g., gowns or coveralls);
  - o low-lint, disposable head covers that cover hair, ears, and if applicable, facial hair
  - o face mask

#### Facilities

- Compounding must occur in either (1) an ISO Class 5 Primary Engineering Control (PEC) **OR** (2) in a dedicated Allergenic Extracts Compounding Area (AECA).
- The PEC or AECA must be located away from unsealed windows, doors that connect to the outdoors, and traffic flow (all of which may adversely affect the air quality).
- Neither the PEC or AECA may be located where environmental control challenges (e.g., restrooms, warehouses, food preparation areas) could negatively affect the air quality.
- The PEC or AECA must be located at least 1 meter away from a sink.
- If used, a PEC must be certified every 6 months, and cleaned and disinfected daily and when surface contamination is known or suspected. Apply sterile 70% Isopropyl Alcohol (IPA) to the work surface between each prescription set.
- An AECA must have a visible perimeter and meet the following conditions:
  - o Access restricted to authorized personnel during compounding.
  - o No other activity permitted during compounding.
  - o All surfaces must be cleanable.
  - o No carpet is allowed.
  - o Surfaces should be resistant to damage by cleaning and sanitizing agents.
  - o Surfaces must be smooth, impervious, non-shedding, and free of cracks or crevices to allow for easier cleaning.
  - o Dust-collecting overhangs (e.g., utility pipes, ledges, windowsills) should be minimized or must be easily cleaned.
  - o Designed and controlled to provide a well-lighted working environment, with temperature and humidity controls for the comfort of compounding personnel wearing the required garb.

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# Allergen Extract Compounding of In-Office Immunotherapy Vials

## USP General Chapter <797> Compliance

- o Work surfaces must be cleaned and disinfected daily and when surface contamination is known or suspected.
- o Apply sterile 70% Isopropyl Alcohol (IPA) to the work surface between each prescription set.
- o Walls, doors, and door frames within the perimeter of the Allergenic Extract Compound Area (AECA) must be cleaned and disinfected monthly and when surface contamination is known or suspected.
- o Ceilings must be cleaned and disinfected when visibly soiled.
- Vial stoppers on packages of conventionally manufactured sterile ingredients must be wiped with 70% Isopropyl Alcohol (IPA) to ensure that the critical sites are wet and allowed to dry before they are used to compound allergenic extract prescription sets.

### Establishing Beyond-use Dates (BUDs)

- The beyond-use date (BUD) for the prescription set must be no later than the earliest expiration date of any allergenic extract or any diluent that is part of the prescription set. The BUD must not exceed 1 year from the date the prescription set is mixed or diluted.

### Labeling

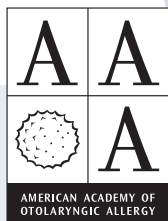
- The label of each vial of an allergenic extract prescription set must display the following prominently and understandably:
  - o Patient name
  - o Type and fractional dilution of each vial, with corresponding vial number
  - o Beyond-use date (BUD)
  - o Storage conditions

### Documentation

All facilities where allergenic extract prescription sets are prepared must have and maintain written or electronic documentation to include, but not limited to, the following:

- Standard Operating Procedures (SOPs) describing all aspects of the compounding process.
- Personnel training records, competency assessments, and qualification records, including corrective actions for any failures.
- Certification reports for Primary Engineering Control (PEC), if used, including any corrective actions for any failures.
- Temperature logs for refrigerator(s).
- Compounding records for individual allergenic extract prescription sets
- Compounding records must include:
  - o Name, concentration, volume, vendor or manufacturer, lot number, and expiration date for each component
  - o Date and time of preparation of the allergenic extracts
  - o Assigned internal identification number
  - o Method to identify the individuals involved in the compounding process and verifying the final compounded sterile preparation (CSP)
  - o Total quantity compounded
  - o Assigned BUD and storage requirements
  - o Results of QC procedures (e.g., visual inspection, second verification of quantities)
- Information related to complaints and adverse events.
- Investigations and corrective actions

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**E**fficacy of immunotherapy depends on reaching and maintaining an optimal dose of immunotherapy in a safe and efficacious manner. The goal of optimal therapy is to affect and maintain an immunologic response to reduce allergy reactivity. The starting dose, as determined by quantitative testing, should be used to begin immunotherapy, but the optimal dose for maintenance therapy would be 5-20 mcg per dose, which is about 1000-2000 BAU per injection and 1000-4000 in more recent practice guidelines.<sup>1</sup> However clinically, the patient may note improvement of symptoms at a “symptom-relieving dose” which may be much lower than scientifically proven immunologic dose. Patients should still be advanced to the maximal tolerated dose or effective dose to obtain clinical immunologic response and overall symptom reduction.

Clinically, all patients may not tolerate dosages at that range and should still be escalated to the highest-tolerated dose. Dosages at this level are more likely to provide immunologic response without significant adverse reaction to obtain appropriate clinical results.

The efficacy of immunotherapy depends on achieving an optimal therapeutic dose for each antigen.

The maintenance dose of allergen immunotherapy must be adequate to achieve optimal clinical results. A consideration when mixing extract is the need to deliver an optimal tolerable antigen. Each antigen contributes to a successful therapeutic outcome.<sup>2</sup>

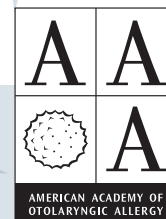
The maintenance concentrate should be formulated to deliver a dose considered to be therapeutically effective for each of its constituent components, and patient’s reactivity. The projected effective dose is called the maintenance goal. Some subjects unable to tolerate the projected effective dose will experience clinical benefits at a lower dose. The maintenance dose is the dose that provides optimal therapeutic efficacy without significant adverse local or systemic reactions. Adjustments of individual dosing can be accomplished with separation of antigens and or dilution/decreased dosing.

<sup>1</sup> Cox L, Allergen Immunotherapy: A practice parameter third update. AAAAI task force report; J Allergy Clin Immunology, 2011, Vol 127, number 1: S1-S55

<sup>2</sup> Hoover H, Leatherman B, Ryan M, McMains K, Veling M. Evidence based dosing of maintenance subcutaneous immunotherapy: a contemporary review of state of the art practice. Int Forum Allergy Rhinol. 2018;8:806-816

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# Duration of Immunotherapy



The purpose of this American Academy of Otolaryngic Allergy (AAOA) clinical position statement is to guide physicians in determining the appropriate duration of specific immunotherapy (SIT). To date, there are no specific tests to help physicians predict which patients will relapse after discontinuation of SIT.

### Evidence:

In two studies examining mite SIT for duration of 1 year or less, efficacy was lost after 1 year.<sup>1,2</sup>

Des Roches et al. conducted a controlled, prospective study to assess the duration of efficacy of specific immunotherapy after discontinuation. The rate of relapse after discontinuation of SIT was significantly higher in the group who received SIT for under 35 months. A longer duration of SIT was associated with increased efficacy.<sup>3</sup>

Durham et al. conducted a randomized double-blind, placebo-controlled cessation study of grass pollen immunotherapy. They showed that, after three to four years of grass pollen SIT, efficacy remained comparable in patients who discontinued SIT and in those who continued

injections. Clinical benefit was observed for at least three years after discontinuation.<sup>4</sup>

The duration of immunotherapy efficacy has also been studied in Hymenoptera hypersensitivity with no clear consensus. Some studies showed that a 3-year duration of SIT was protective, whereas others showed better outcomes in those treated with at least a four-year duration. Relapse rate and severe reactions are greater in those patients whose duration of SIT was less than 5 years. Multiple studies suggest that a 5-year duration of immunotherapy for Hymenoptera hypersensitivity is sufficient in most patients.<sup>5,6</sup>

### Recommendation:

In summary, the rate of relapse decreases in relation to the duration of treatment, but data is lacking to accurately determine the ideal duration of SIT. The best available evidence supports a minimum of 3-5 year duration of SIT. The decision to discontinue specific immunotherapy is made between the physician and patient and must be individualized.

- 1 Price JF, Warner JO, et al. A controlled trial of hyposensitization with adsorbed tyrosine Dermatophagoides pteronyssinus antigen in childhood asthma: in vivo aspects. *Clin Allergy* 1984; 14:209-219.
- 2 Smith A. Hyposensitization with Dermatophagoides pteronyssinus antigen: trial in asthma induced by house dust. *BMJ* 1971; 4:204-6.
- 3 Des Roches A, Paradis L, et al. Immunotherapy with a standardized Dermatophagoides pteronyssinus extract. V. Duration of the efficacy of immunotherapy after its cessation. *Allergy*. 1996 Jun; 51(6): 430-3.

- 4 Durham SR, Walker SM, et al. Long-term clinical efficacy of grass-pollen immunotherapy. *N Engl J Med*. 1999 Aug 12; 341(7): 468-75.
- 5 Cox L, Nelson H, et al. Allergen immunotherapy: a practice parameter third update. *J Allergy Clin Immunol*. 2011 Mar; 127(3): 840.
- 6 Penagos et al Duration of Allergen Immunotherapy for Long Term Efficacy in Allergic Rhinconjunctivitis. *Current Treat Options Allergy*. 2018; 5(3): 275-290.

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# Home Subcutaneous Immunotherapy

The American Academy of Otolaryngic Allergy (AAOA) encourages the preferential practice of administering subcutaneous immunotherapy in a medical office setting with professionals trained in the recognition and management of anaphylactic reactions.

The AAOA also recognizes the need for patients to make decisions affecting their personal healthcare choices, including the choice of home-administered immunotherapy. The physician should assess the risks and benefits of in-office versus home-administered immunotherapy for each individual patient, taking into account the severity of allergic disease, coexisting medical conditions and medications, and other relevant individual patient characteristics. The risk and benefits should be discussed with each individual patient and informed consent should be obtained.

- The relative safety of home-administered immunotherapy when patients are properly selected has been reported.<sup>1, 2</sup>
- Some patients, due to life factors that limit their ability to follow a regime of immunotherapy injections restricted to a medical office environment, may have access issues to allergy care.
- Medical professionals regularly assess the risks and benefits of a particular medical intervention, explain these risks and benefits to a patient, and allow the patient to make decisions on which medical treatments to accept in an informed consent process.
- If a medical professional determines a particular patient has an acceptable risk/benefit ratio to allow the option of home immunotherapy, and the patient decides to proceed with the option of home immunotherapy, the physician should provide clear directions and training on the proper technique for handling and administering the immunotherapy products. The patient should also be trained in the recognition and treatment of potential adverse events, including the availability and use of epinephrine auto-injectors. All injections at home should be given in the presence of another responsible adult provided with instructions in the recognition of potential anaphylaxis, and basic initial treatment of anaphylaxis, including epinephrine auto-injector administration and contacting emergency services.

1 Hurst DS, Gordon BR, Fornadley JA, et al. Safety of home-based and office allergy immunotherapy: A multicenter prospective study. *Otolaryngology–Head & Neck Surgery* 1999;121:553-61.

2 Schaffer, FM, Naples, AR, Ebling, M et al. The safety of self-administered allergen immunotherapy during the buildup and maintenance phases. *International Forum of Allergy & Rhinology* 2015; 5 (2): 149-156

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# State Regulations on Staffing, Training Requirements, and AP/AH Scope of Service

Otolaryngic allergists need to be aware of their individual state regulatory laws regarding the practice of allergy in their location. This applies to scope of practice, licensure, and dispensing laws.

- When midlevel providers are involved in delivering allergy care, state laws regarding location of practice, level of independence, and type of training should be followed.
- Regulatory requirements for ancillary staff regarding level of training required for allergy testing and administration of injections vary by state.
- Some states have medication dispensing laws that may apply to immunotherapy (i.e., sublingual or subcutaneous).
- Some states have requirements for basic and advanced life-support training of allergy providers and staff.

### Scope of Practice

- Nurse practice laws and regulations are specific to each state.
- AANP offers quick reference guide for licensure and regulatory requirements, as well as practice environment details, for all 50 states and the U.S. Territories. Downloadable State Regulatory Map available at [www.aanp.org](http://www.aanp.org).
- AAPA's webstore offers "PA State Laws and Regulations" including all 50 states and the District of Columbia. [www.AAPA.org](http://www.AAPA.org) offers a synopsis of each

state's PA practice act, including scope of practice, prescribing and supervision, among other topics that cover PA practice.

- The AAOA recommends checking with state nursing board to confirm scope of practice and whether an NP/PA can supervise another staff member testing or treating.
- Medical Assistant and Nurse laws are specific to each state.
- For medical assistants, refer to the CAAHEP Standards for the Accreditation of Educational Programs in Medical Assisting. Appendix B contains the Core Curriculum. This delineates what medical assisting students in CAAHEP-accredited programs must know to be able to complete the program. This program varies between states and can change so please refer to the above for your state regulations.
- For examples, see below:
  - New York and Connecticut laws do not permit physicians to delegate to medical assistants any administration of medication, including by means of injection.
  - The laws of Washington, California, Florida, Maryland, and South Dakota are specific. They do permit physicians to delegate to medical assistants the administration of IM, subcutaneous, and ID injections. There is no language in the laws of these states that forbids medical assistants from being delegated the administration of allergy injections.

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The laws of some states require the delegating provider to verify the dosage and identity of the medication before it is administered by the medical assistant.

- The American Academy of Nursing has a “Policy and Advocacy” section on its website [www.aannet.org/](http://www.aannet.org/). Regulations may also be hospital specific as some hospitals only employ RNs and do not have to employ LPNs.

All personnel performing shots or testing should have formal allergy training, as well as training in anaphylaxis

management. All allergy test interpretation, dose calculation, and vial preparation should be performed in conjunction with a physician practicing otolaryngic allergy.

For further information on supervision and “incidence to,” please refer to the Clinical Care Statement on *Allergen Extract Compounding of In Office Immunotherapy Vials* and the AAOA’s Practice Resources Toolkit at: [www.aaoallergy.org/practice-2/practice-resource-tool-kit/](http://www.aaoallergy.org/practice-2/practice-resource-tool-kit/)

### *As an example, NP Scope of Practice is defined as:*

<b>Full Practice:</b>	Evaluate patients, diagnose, order and interpret tests, initiate and manage treatments under the exclusive licensure authority of the state nursing board
<b>Reduced Practice:</b>	Reduces the ability to engage in at least one element of NP practice (above) and requires collaborative agreement with an outside health discipline for the NP to provide patient care
<b>Restricted Practice:</b>	Restricts the ability to engage in at least one element of NP practice (above) and state requires supervision, delegation, or team-management by an outside health discipline to provide patient care.

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# Nurse Practitioners and Physician Assistants in the Practice of Allergy in the Otolaryngology Office



**T**he American Academy of Otolaryngic Allergy (AAOA) recognizes the training and expertise available from within the Nurse Practitioner (NP) and Physician Assistant (PA) communities. An increasing number of otolaryngology practices are finding these practitioners to be valuable assets for extending the reach of the practice in the community.

The AAOA, through its stated mission of supporting otolaryngologists who practice allergy, is prepared to assist in the training and continuing education of NP/PAs associated with an allergy practice. It is understood that any training or support of NP/PA training is considered an extension of, and in conjunction with, the training and support of the otolaryngologist who is practicing allergy.

NP/PAs may interact with otolaryngic allergy in several different ways, depending on the preference of the otolaryngic allergy physician, the applicable state laws, and the training of the practitioners themselves. *A recurring theme of this statement is that applicable state laws vary greatly from state-to-state, and from NP to PA within states.* Practice situations described in this document that may sound reasonable and be perfectly reasonable in one state may be illegal across the state border.

It is vital to consult federal and state regulations (see link below) when considering the addition of a NP/PA to the practice. <https://www.aanp.org/advocacy/state/state-practice-environment>

### **Physician extenders in otolaryngology with minimal contact with allergy care.**

A common scenario is NP/PA with no specific allergy training working in an otolaryngology clinic. This would be analogous to a physician partner in the practice who has no training or specialty interest in allergy, such as a head and neck specialist. The physician extenders should give no shots and would refer patients suspected of allergic disease to the otolaryngic allergy practitioner or 'team' in the office as needed.

The critical consideration with this arrangement is whether the physician extender could be the only practitioner in the office when a medical assistant or nurse is giving shots? For this to be a safe practice, the NP/PA must have at least Basic Life Support (BLS) and an understanding of the emergency practices involved in treating anaphylaxis. Additionally, the state regulatory board must permit the NP/PA to be the provider 'authorizing' and responsible for the therapy.

This means that even a NP/PA who is not primarily involved with allergy testing or treatment must have a basic knowledge of emergency procedures and be authorized by the state and the supervisor's guidelines to be the practitioner in the office while immunotherapy is being administered.

### **Physician extenders who provide allergy testing and treatment**

While it may not be economically viable to have a trained physician extender acting purely in the role of administering allergy shots or testing, a small practice may find this an expedient role for a portion of the physician extender's time. In this situation, training from both the otolaryngic allergy physician and supplemental education from the AAOA is considered necessary and prudent, much as a nurse or medical assistant (MA) would be trained prior to assuming testing and treatment duties. Essentially all states would permit physician extenders to fill the role of MA or allergy nurses; the question is to what extent they may practice with autonomy.

It is the position of the AAOA that, while a well-trained physician extender may provide allergy diagnosis and testing in an autonomous situation, that all functions of test interpretation, dose calculation, and vial preparation should be carried out in conjunction with, and under the direct supervision of, the physician practicing otolaryngic allergy.

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# Available AAOA Resources

## COVID-19 Resources

- **Resuming SCIT during COVID-19 Pandemic:** <https://aaoallergy.org/allergy/resuming-scit-during-covid-19-pandemic/>
- **Telemedicine Tool Kit:** <https://aaoallergy.org/advocacy-updates/telehealth-toolkit-for-providers/>
- **Telehealth Coding:** <https://aaoallergy.org/advocacy-updates/covid-19-telehealth-coding/>
- **Regulatory/Congressional Updates:** <https://aaoallergy.org/advocacy-updates/>
- **AAOA Zoomcast Series**—Just in Time Content

Key AAOA leaders discuss hot topics from telemedicine and how to re-open allergy to issues to consider as you re-open your practice from PPE and patient and staff

safety to how to re-engage patients and re-build cash flow.

- o Surgical Priorities
- o Managing Allergy Patients During the COVID Era—Rebooting Practices After the Pandemic
- o Allergy Practice Reboot During the COVID Era
- o Telemedicine During the COVID Era and Beyond
- o Jump Starting Your Practice When COVID-19 Restrictions Are Lifted
- o COVID-19 and Anosmia
- o Physician Wellness / Physician Burnout
- o Re-Onboarding Staff—Restarting Your ENT Practice

## AAOA Practice Resource Tool Kit

You can download and print the entire **AAOA Practice Resource Tool Kit** and **Sample Office Forms** or each tool individually.

*By viewing or downloading the AAOA Practice Resource Tool Kit you understand and agree that the materials presented in this tool kit are intended as resource only and should not be construed as guidance.*

- |  |   |
|--|---|
| <input type="checkbox"/> Otolaryngic Allergy Start Up Checklist                    | <input type="checkbox"/> CPT Coding Guidance  |
| <input type="checkbox"/> Staffing Considerations                                   | <input type="checkbox"/> SLIT Cost Calculator   |
| <input type="checkbox"/> Staffing Considerations: Supervision                      | <input type="checkbox"/> USP General Chapter <797> Pharmaceutical Compounding—Sterile Preparations  |
| <input type="checkbox"/> Physical Space & Equipment Needed for the Allergy Patient | <input type="checkbox"/> Resources: Gloved Fingertip & Thumb Sampling, Media Fill, Incubators       |
| <input type="checkbox"/> Key Impactors of Patient Flow                             | <input type="checkbox"/> Section 21. Compounding Allergenic Extracts from USP General Chapter <797> |
| <input type="checkbox"/> Tip Sheet for Evaluating Payor Contracts & Policies       | <input type="checkbox"/> Patient Resources  |
| <input type="checkbox"/> Marketing Your Practice                                   | <input type="checkbox"/> Sample Office Forms  |
| <input type="checkbox"/> Allergy Coding  |   |

## USP General Chapter <797> Compliance Resources

- USP General Chapter <797> Compliance Tools: <https://aaoallergy.org/?s=usp>

AAOA has developed a compliance module and negotiated a reduced AAOA member rate for the gloved thumb/fingerprint and sterile compounding test kits, more information can be found here:

<https://aaoallergy.org/advocacy-updates/usp-general-chapter-news-media-fill-test-kit/>

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