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IMMUNOTHERAPY (ALLERGY SHOTS)

If you are thinking of starting allergy shots, please consider the following:

1) **For what conditions can allergy shots be helpful?** Allergy shots are given to help in the management of allergic rhinitis (nasal allergy symptoms), recurrent-chronic sinusitis, allergic conjunctivitis (ocular allergy eye symptoms), allergic asthma, and stinging insect allergy.

2) **When should starting allergy shots be considered?** A patient is a good candidate for immunotherapy injections if a) medications have proven suboptimally helpful in controlling symptoms, b) medicines have worked well but have caused unacceptable side effects, or c) drugs have been found to satisfactorily control symptoms and are well tolerated but the patient desires to reduce the number of medicines or number of days a year or number of times a day that they have to take their allergy-related drugs.

3) **What is in the allergy shot extracts?** They contain the aeroallergens (tree-grass-weed pollens, mold spores, animal dander, and house dust particles) to which you were deemed allergic based on your symptoms and skin tests.

4) **How do allergy shots work?** By injecting increasing amounts of aeroallergens the patient develops decreasing sensitivity with subsequent decreasing symptoms and/or decreasing need for medications. In many respects, allergy shots work similar to immunizations for infectious diseases wherein injection of DPT, MMR, Polio, Hib, Hepatitis B, chicken pox, influenza, etc., will result in resistance to the adverse effects of those infectious agents or their products.

5) **How often do allergy shots work?** Our experience has been that 90-95% of patients who complete at least one year of immunotherapy injections think the shots have been helpful enough to have been worthwhile.

6) **How fast do allergy shots work?** In the majority of patients who get the shots once a week in the "build-up" phase (see below), it takes several months before the shots are perceived as being helpful. There are exceptions in both directions with a minority of patients thinking the shots are helpful after just several weeks to a few months and other patients not being certain of benefit until they have been on the shots 12-18 months. The injections will usually be discontinued if the patient hasn't noticed benefit by 15-18 months.

7) **How well do allergy shots work?** The answer to this is highly variable. At either extreme are a minority of patients who receive no benefit versus those where the shots have been so helpful that they no longer have symptoms and no longer need allergy medications. In between are the majority of patients who are feeling better and needing less allergy drugs. These patients will often state that they are feeling 50-60-70-80% better. Some patients who perceive the allergy shots as having been worthwhile still need just as many medicines, just as many times a day and just as many days a year, but the benefit of the shots

has been that now their medicines work well whereas before the shots the patient felt that no medicine they tried ever seemed to help.

8) **How long does it take before the allergy shots achieve peak effectiveness?** In the majority of patients there is continued improvement for the first 3 to 4 years before the benefit derived from the shots plateaus.

9) **Can I get the shots somewhere other than my allergist's office**? Yes. But the shots have to be given in a medical care facility where a physician, physician assistant(PA), or nurse practitioner(APRN) is present and immediately available. If you prefer or need to get the shots somewhere other than in our offices, then you need to indicate such in the appropriate place at the end of this handout. We will prepare the immunotherapy extract and mail the first bottle(s) to the designated facility with forms on which to record the details of each injection and detailed instructions on how to administer the shots. You will, obviously, need to contact the office in which you would like to get the shots to see if they would be willing to help you in this regard. In our experience most doctors are willing to give such assistance. Whether you get the shots in our or another office, the extracts will usually take no more than a week to prepare. You will be notified when the extracts are ready. We do not allow patients to receive immunotherapy injections a) at home, b) at places of employment by a company nurse where a physician, PA, or APRN isn't immediately available, and c) at college/university student health centers where a physician, PA, or APRN isn't immediately available. No exceptions please.

10) **If I get the shots in an Asthma & Allergy PA office, when can I get them?** You can get the shots in our offices without an appointment at the following times:

Lawrence		**Topeka**	
Monday	8:30AM-12:00PM 1:00PM-4:45PM	Monday	Noon-4:30PM
Tues - Thur	8:30AM-4:45PM		
Friday	8:30AM-12:00PM 1:00PM-4:45PM	Thurs, Friday	9:00AM-12:00PM 1:30PM-4:30PM
Saturday	8:30AM-11:30AM		

Office closings will be posted whenever possible at least 30 days in advance. Unfortunately, there may be rare closings without advance notice such as related to illness or death in the family of the physician scheduled to be in the office that day. Please consider providing us your email address or cell phone number which allows us to alert you via text/email as soon as we know closings will occur.

11) **How often are the allergy shots given?** Most patients get the shots once a week during the "build-up" phase, which takes several months (an average of 6-10). During this build-up phase the dose or concentration or both of the allergy shot extract is progressively increased according to the tolerance of the patient to a "maintenance" dose which the patient will receive shot after shot. This maintenance dose varies from patient to patient and even in the same patient from time to time. Once the maintenance dose has been reached the shot frequency is usually reduced to every 2 weeks for 1.5 years, then every 3 weeks for a year, then once a month.

12) **How are the allergy shots given?** Allergy shots are given in the arm (on the outer aspect) between the elbow and the shoulder with short (1/2 inch), thin (25-27 gauge) needles.

The aeroallergens to which you are allergic will be mixed in a concentrated form in a bottle that will have a red cap and be labeled as having a concentration of 1:1. Three weaker bottles will be made

from the strongest bottle, with concentrations of 1:10 (yellow cap), 1:100 (blue cap) and 1:1000 (green cap). Our intent is to give the shots according to the schedule listed in the table below. However, you need to keep in mind that this proposed protocol is modified in almost all patients for multiple reasons so that it merely represents a convenient starting point from which an almost infinite array of variations arises. The doses in the table are in units of ml(cc). Not all allergens can be mixed with every other allergen. Because of this, when a patient is allergic to allergens that cannot be mixed together, 2 or 3 sets of red, yellow, green and blue vials will be required. When this occurs, the patient will receive 2 or 3 shots at each visit instead of one. Two or 3 shots may also be needed when a patient is allergic to so many allergens that one vial cannot contain all of them at sufficient concentration.

COLOR	GREEN	BLUE	YELLOW	RED
CONCENTRATION	1:1000	1:100	1:10	1:1
SHOT #1	0.05	0.05	0.05	0.05
SHOT #2	0.10	0.10	0.07	0.07
SHOT #3	0.20	0.20	0.10	0.10
SHOT #4	0.35	0.35	0.15	0.15
SHOT #5	0.50	0.50	0.25	0.25
SHOT #6			0.35	0.35
SHOT #7			0.50	0.50

13) **How long will the allergy shot program last?** No one is quite sure what the optimal duration of immunotherapy should be. In this office, once a maintenance dose has been achieved (such as 0.50 ml of the red-capped 1:1), then this dose is given (if it continues to be tolerated) with decreasing frequency (as mentioned in paragraph 11 above) but for a total duration of **4 years**. At that time your allergist will probably suggest that the allergy shots be discontinued as you've possibly obtained all the benefit you are going to get from them and further administration may not lead to further benefit. At that time, probably 95% of patients are eager to stop their shots. A small minority of patients may continue the injections longer if they so desire, especially if they've been on immunotherapy before and this is their second "go-around". These patients frequently are reluctant to discontinue the shots and run the risk of relapsing again off the shots with subsequent possible need for an allergy skin test update and re-initiation of injections at a once a week frequency. Many such patients think continuing to get shots once a month is less a concern than the possible risk of relapse off them.

14) **How much do allergy shots cost?** Allergy shots are not inexpensive and are prepared individually for each patient's unique allergic sensitivities. There are two types of charges for the injections, one for the extract itself and the other for the extract administration(e.g. syringe, nurse time, etc.) When this consent form is signed to start shots, there will be an up front charge for the first batch of extract approximating $830-964(the cost of 4 vials) for patients who need only one shot each visit. For patients who need two shots each visit this up front charge for the first batch(8 vials) will be higher and range from $1660-1928. For patients who need 3 shots, the first batch(12 vials) costs $2490-2892. The first batch of 4, 8 or 12 vials will last at least 8-9 months. You will be charged for this first batch of extract even if you don't complete the shot program once you have chosen to initiate it. After the initial 4, 8 or 12 vials are completed there will be a charge thereafter for maintenance vials of extract at an approximate cost of $392-512(single vial), $784-1024(2 vials), or $1176-1536(3 vials) every 4-6 months. The second, or administration charge, is $28 per shot(or $32 if 2 or 3 shots are required) in our offices. Other facilities where the shots might be obtained may charge more or less than $28 or $32 for administering the shots. Most health insurance policies cover immunotherapy injections but you will need to consult your policy description or company representative for details. The CPT code for allergy extract is 95165. The code for administration of a single injection is 95115, and 95117 for 2 or more injections.

Number of shots patient will receive	Number of vials mixed when shots begin	Charge for the initial batch of vials	Number of maintenance refill vial(s) needed every 4-6 months	Cost of maintenance refill vial(s) every 4-6 months	Cost of administration of shot(s)
1	4	$830-964	1	$392-512	$28
2	8	$1660-1928	2	$784-1024	$32
3	12	$2490-2892	3	$1176-1536	$32

15) **What kind of side effects can occur from the allergy shots?** There are 2 main types of reactions that can occur. The first is called a **"systemic"** or **"generalized"** reaction. This reaction is manifested by some or all of the following symptoms: itching and/or redness of skin, a sensation of generalized warmth of skin, hives (welts), angioedema (swelling around the eyes or of the lips-tongue-throat), wheezing, coughing, chest tightness, a feeling of shortness of breath, sneezing, runny nose, nasal congestion, itching of the nose-palate-throat-eyes-ears, ocular tearing, nausea, vomiting, abdominal cramping, diarrhea, dizziness, light-headedness, and, in severe cases, loss of consciousness and even, rarely, death. If such symptoms should occur in the office then **immediately** notify an office staff person.

The majority of systemic reactions will start in the first 20-30 minutes after the shot. This is why we require patients receive their immunotherapy in a doctor's office and why we require the patient to wait in the doctor's office at least 30 minutes after each shot so that such reactions can be evaluated and treated before the patient leaves. Repeated failure to wait 30 minutes after each shot will result in the shots being discontinued.

Because a systemic reaction can occasionally begin more than 30 minutes after a shot(when the patient has usually already left the office), patients are **required** to have with them at the time of the shot (and are **strongly** urged to carry with them until 1 hour after the shot was given) an epinephrine injection for self-administration. These "delayed"(onset after 30 minutes) systemic reactions are generally not severe compared to those which begin within the 30 minute waiting period. Self-injectable epinephrine can be obtained by prescription through most pharmacies.

We obviously want you to know by the time of your first shot how to use the epinephrine injection. We, your pharmacy, and each epinephrine auto-injector's web site can provide a demonstration. It should be used if, after leaving the office (primarily in the first hour after the shot), the patient experiences shortness of breath, coughing, wheezing, chest tightness, a sensation of swelling in the throat or tongue, a change in level of consciousness (such as disorientation or confusion), or if gastrointestinal symptoms develop, such as vomiting, abdominal cramping, or diarrhea. If there is uncertainty in your mind as to whether it should be used or not, it would be better to err on the side of doing so, rather than not. If used, return to the office where you received your allergy shot (or, if closer, go to the nearest emergency room). The development of itchy skin or hives (welts) alone, without the other symptoms mentioned above, can be treated with an antihistamine (preferably in liquid form), and the use of epinephrine is usually not required (although we still would like you to inform us immediately).

Systemic reactions are quite infrequent, occurring in approximately 1 in 500 to 1 in 1000 shots. The majority of patients will get approximately 90-100 allergy shots during the 4-5 years that they are getting injections. The vast majority of systemic reactions are mild and require no more than an oral antihistamine syrup and/or the use of 2-4 puffs of a bronchodilator asthma inhaler. Infrequently the patient may need to be given an injection of epinephrine. The patient usually will need to be observed in the office an extra 30 minutes or longer, depending on the severity of the reaction and how quickly it responds to the treatment. The occurrence of a systemic reaction will necessitate a decrease in the dose of the next injection.

Because treatment of systemic reactions may require the use of epinephrine, and because beta-blocker medicines (used for treatment of angina, patients who have survived a heart attack, hypertension, cardiac arrhythmias, migraine headache and glaucoma, etc.) block the effects of epinephrine, we cannot give allergy shots to patients on beta-blockers.

Because systemic or generalized reactions are more likely to occur in asthmatics whose asthma is being suboptimally controlled, and because some asthma patients aren't always aware how bad their asthma is, we require all patients of school age or older getting shots in our office to do PEFRs (Peak Expiratory Flow Rates) prior to each shot. We **strongly** encourage all other physician offices giving our patients allergy shots to also check PEFRs prior to each shot. If this isn't being done, please contact our office.

The second, more likely and less worrisome, type of side effect from allergy shots is the "**local**" reaction. This is a reaction that occurs at the injection site within minutes to a few hours after the shot and lasting for an hour or so up to a few days. The patient may develop one or more of the following: redness, warmth, swelling, tenderness, and itching. Almost all patients will have such local reactions at one time or another during the course of their immunotherapy. These reactions may be more likely to occur during peak allergy seasons or during the "build-up" phase of their immunotherapy. We categorize local reactions into one of three types: a) not bothersome and therefore well tolerated, b) bothersome but tolerable, and c) not only bothersome but also poorly tolerated. Each time when you go in for your allergy shot, you need to report to the nurse giving the shot what type of local reaction you had, if any, with the preceding shot. The nurse giving your shot has been advised on how to adjust your dose depending on which type of reaction you experienced.

The occurrence of both **"local"** and **"systemic"** allergy shot reactions can be reduced by pre-medicating with an antihistamine(e.g. Zyrtec, cetirizine, Claritin, loratidine, Allegra, fexofenadine, Clarinex) the day of allergy shots(J Allergy Clin Immunol 128, No. 4, p 907, 2011). Please ask if you are uncertain as to what dosage of antihistamine is appropriate.

16) **What happens if I miss a shot?** The nurse giving you the allergy shots has been given instructions as to how to deal with missed shots. Your shot dosage may be decreased depending on how long it has been since your last shot.

17) **What happens after the shots are discontinued?** If the entire allergy shot program (usually 4-5 years) isn't completed, symptoms frequently worsen a year or so after stopping the injections. By the time a patient has had allergy shots for 4-5 years, enough people can discontinue them and maintain their improvement for extended periods of time (or even indefinitely), that it seems worthwhile to attempt such. However, even after 4-5 years of immunotherapy, some patients will quickly relapse off shots and may need to be skin tested again with re-initiation of immunotherapy. Obviously, if we could predict which patients would do well off shots for long periods (or indefinitely) and who wouldn't, then we would know in what patients it would be appropriate to discontinue shots and who should continue. Unfortunately, we are unable to so predict. This is why some patients elect to continue immunotherapy every 1-2 months indefinitely.

18) **Can allergy shots be continued in pregnancy?** Although we would rarely start immunotherapy on a patient who is pregnant, extensive experience with allergy shots in pregnant patients has documented its safety such that there is near consensual agreement among allergists that if a patient is already on immunotherapy and becomes pregnant that there is no need to discontinue injections. If the patient is on a maintenance dose when the patient becomes pregnant, then that dose will probably be continued as is. If the patient is still in the build-up phase of immunotherapy at the onset of pregnancy, then that dose may be held steady until after delivery (at which time attempts may be made to raise the dose).

19) **<u>THE NURSE WILL NOT GIVE YOU AN ALLERGY SHOT IF</u>**:

a) you have a fever,
b) you are taking a medicine in order to suppress your fever,
c) you are on a short course of prednisone/prednisolone/Prelone/Pediapred for asthma,
d) your PEFRs are reduced more than 20% of your average,
e) you are wheezing or coughing,
f) you are feeling sick in general,
g) you are taking a betablocker medication, or
h) you don't have your injectable epinephrine. In this case there is, however, the option of waiting 1 hour in the office after the shot, if the shot can be given 1 hour before the office closes.

20) If the patient is a child, and if the parent or legal guardian does not accompany the child to the office for the allergy shot, then the child must be accompanied by someone 16 years old or older. In this case, our office needs to have written permission signed by the parent or legal guardian (given to the shot nurse) stating this is the desire of the parent or legal guardian.

Please contact your carrier to verify coverage and/or benefits for extract, administration of extract, and self-injectable epinephrine.

I acknowledge the fact with my signature that I am responsible for payment for allergy extract. I will be responsible for charges my insurance company does not authorize or cover. I have read and understand the above and consent to immunotherapy injections (allergy shots) being given to me (or my child). I have been given the opportunity to ask any and all questions that I may have and am satisfied that they have been fully answered. I consent and authorize the treatment of any reactions that may occur as a result of an allergy shot.

_____ _____ _____ _____

SIGNATURE (patient or legal guardian) DATE SIGNATURE (person financially responsible for an adult patient, e.g. parent of an adult student) DATE

_____

PATIENT NAME (PRINTED)

Where do you desire to receive your allergy shots?

☐ **Asthma & Allergy Associates, Lawrence office**
☐ **Asthma & Allergy Associates, Topeka office**
☐ **Another location:** Dr._____ will oversee the shot administration. This doctor's address and phone are: _____.

Receive Text/Email Closings Notifications

Please enter the following information if you wish to receive text and/or email notifications regarding office closings:
Cell phone carrier(e.g. ATT):_____ Cell phone number(xxx)xxx-xxxx:_____
Email address:_____

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