

PATIENT INFORMATION ON IMMUNOTHERAPY (Allergy Shots) AND INFORMED CONSENT FOR TREATMENT- Dr. Michael Vaughn

1. Immunotherapy or “Allergy shots” have been proven beneficial for nasal allergies, asthma, eczema and stinging insect allergy and may also decrease the incidence of sinus infections. Allergy shots are typically offered only to allergic patients who have severe symptoms that affect their quality of life. Most allergic patients do not need allergy shots for treatment of their symptoms. However, if medications and environmental changes are not sufficient to minimize symptoms, then allergy shots may be the only effective treatment option available. In persons who require multiple medications to control their symptoms, allergy shots may also be a cost saving option.

2. Immunotherapy works by gradually “turning off” allergy to plant pollens, molds, dust mites, animal dander and insect venom. During the “build-up” process, the allergen is usually injected ***two times each week*** in progressively stronger doses over a 6-month period until the top dose “maintenance” vial is reached. After reaching the maintenance dose, the time between each injection can then be increased with the goal of making the routine maintenance shot interval ***twice per month***. In our office, a 3-year course of allergy shots, given twice per month, typically results in a complete loss of allergen sensitivity however; an occasional patient may not be completely “cured” and require more than 3 years of treatment. Unfortunately, up to 50 % of patients who suffer from Allergic Rhinitis (AR), caused by allergic antibodies (IgE), also suffer with “Non-allergic Rhinitis” (NAR). NAR is caused by an unusual sensitivity to environmental irritants such as: tobacco smoke, perfumes, strong chemical odors, diesel fumes, spicy food, dust and many other irritants. Although the symptoms of NAR are similar to those of AR, NAR will not improve on allergy shots and NAR symptoms may require medications for control.

3. To obtain the best results, a patient needs to receive maintenance shots twice per month. Missing shots for more than one month may require a temporary dosage reduction, but missing shots for more than 6 weeks will typically necessitate a full re-start. Annual skin testing is recommended to judge the effectiveness of the shots since over time; skin testing reactions are expected to disappear. The results from each annual skin test are used to modify the doses of allergens contained in the shots (if necessary). The allergy shots are typically stopped when the skin testing is negative for more than 1 year to the patient’s main allergy trigger(s).

4. Immunotherapy injections may be associated with various types of side effects. Side-effects are usually more common in the most severely allergic patients and in those with asthma. The most common side effect is swelling and inflammation (tenderness) at the injection site. These “local” reactions almost always improve over time. Allergy shots may occasionally be associated with more serious generalized “systemic” reactions (**anaphylaxis**). Signs or symptoms of these reactions may consist of: itching away from the injection site, hives, body tissue swelling (distant from the injection site), asthma (new onset coughing, wheezing or chest tightness), abdominal pains, diarrhea, dizziness and even loss of consciousness. Although our office is prepared to treat any serious shot reaction that may develop, if the allergic symptoms do not respond quickly to our treatment, it may be necessary to transport you by EMS to the near-by Baptist or Methodist Hospital Emergency rooms for further monitoring.

5) Data from large studies has revealed that most serious allergic reactions occurred within 30 minutes after an injection. For this reason, all patients are required to remain on-site for 30 minutes after their allergy shot. In May 2015, we looked at the medical records from all allergy shots we administered in 2014. We found that about 1 out of every 95 patients who received allergy shots developed a systemic allergic reaction (anaphylaxis).

These reactions usually occurred following a shot administration from the strong 3rd or 4th vials. While these reactions were typically mild and reversed quickly with treatment, severe allergic reactions resulting in death have occurred following allergy shots. Because serious reactions can develop hours after a shot, every person receiving allergy shots is required to carry an epinephrine self-injector on the day of the injection (***we will not administer an allergy shot to anyone who is not carrying their EpiPen***). “Home” or self-administered allergy shots and “allergy drops”, offered by some non-Allergist physicians, are typically formulated using much lower concentrations of allergens than the “in-office” shots given by Allergists. As a result, these experimental treatments are less effective for symptom control than “full dose” allergy shots and will typically not cure allergic sensitivities. The FDA has only approved oral (sublingual) immunotherapy for grass, ragweed and dust mites.

6. **“RUSH” allergy shots are available at our office.** This treatment option is offered as a convenience to those who would otherwise have difficulty with the typical build-up schedule. With RUSH, 7 build-up injections are given in a three-hour session. In our clinical experience, “RUSH” treatment has been as safe as “conventional” treatment. In a 2004 medical record review, we found that among 255 patients who had completed “RUSH” with the first 2 build-up vials, only one allergic reaction occurred. RUSH is currently only available for the 2 weakest allergen dilution vials. Although “RUSH” build-up can help reach the maintenance dose sooner, RUSH offers no long-term advantage over our “conventional” slower injection protocol and is simply a convenience option that reduces the number of office visits. We have found that when certain medications (Antihistamines, Pepcid and Singulair) were given prior to allergen injections, these ***“pre-meds”*** reduced the frequency (and possibly the severity) of shot-induced allergic reactions and so we strongly recommend that all persons on allergy shots, even those choosing the “conventional” build-up protocol, take pre-meds on the day of an allergy shot. For patients with asthma, using an albuterol inhaler before every allergy shot is recommended.

7. **Fees for services:** Alamo Allergy and Asthma Associates charge a fee for mixing the bottles of allergy extract (we purchase our allergens from ALK – Abello). In addition, there is usually a shot administration fee each time an injection is given. (RUSH-allergy shots are typically billed as “time in our office” and you are not charged for each individual shot). Your insurance may require you to pay a co-pay each time you see us for medical care but there is no “office visit” charge for an allergy shot. ***Allergy shots are not scheduled***; they are given on a walk-in basis as “first-come-first-served”. Although we are contracted with almost all insurance companies, coverage for allergy shot treatment varies. You are responsible for understanding the limitations of your plan. If your insurance benefits change during the process of receiving allergy shots, you are also responsible for immediately providing us with this updated information. If you choose to discontinue your allergy shots, there is no refund for any unused portion of the allergen mixture.

*** I am requesting to receive Immunotherapy (allergy shots) under the supervision of Alamo Asthma & Allergy Associates. I have read and understand the risks and benefits of allergy shots and all questions have been answered to my satisfaction.**

Patient Name _____

Date _____

Patient Signature _____

(Form revised 05/2023)

Allergy Shot Costs - What You Need to Know.

Dr. Michael P. Vaughn

Immunotherapy (IT), commonly referred to as “Allergy shots”, are specifically formulated for each person based on their allergy testing results. Our office provides only 2 types of IT serums: 1) Environmental allergens treatments, 2) Fire Ant Venom treatments. The allergens chosen to be added to your IT mix are typically only those that the physician judges to be the most clinically relevant (important) for achieving a good outcome *For persons with multiple allergic sensitivities, not all the allergens that are positive on your skin test are typically in your shot.

It is your personal responsibility to investigate and understand how your Medical Insurance Provider will manage our billing for your services. There are 2 separate charges that are incurred when allergy shots are started. Initially, a 10cc “maintenance vial” of Serum, called the 1:1 dilution, is prepared by mixing together concentrated individual allergen extracts. Using a portion of the maintenance vial, 3 or 4 weaker concentration vials (dilutions) are then made. Allergy shots are started from the weakest dilution (1:1000) and progressive up-dosing is done, often at each shot visit. As the “Build-up” injection process progresses, if the shots are well tolerated and no slowing is needed, the stronger allergen dilutions are successively used until the 1:1 dilution is finally reached. After reaching your target dose from the 1:1 vial, usually 0.5cc for most adults, this dose is then used (typically twice per month, for 3 years) until shots are discontinued. Your insurance company will be billed for the number of shots that we anticipate you will need **if** the build-up process is not slowed down by any adverse reactions to any doses given. If, due to shot reactions, you need to receive more shots that is anticipated, you will not be billed for any extra IT serum until your maintenance vial is fully consumed or expired. Your insurance will be charged only for the anticipated number of shot doses specified in our office IT injection protocol; for a new IT start kit, there are 10 anticipated shots from each of the 4 dilution vials and 17 maintenance shots are typically left-over in the 1:1 vial after the dilutions are prepared ***Typically, there are 57 doses (billing units) in each new kit we make.** Two serum kits are often required for effective treatment, especially if mold allergy is clinically relevant or when skin testing to grasses was atypically reactive and these need to be given separately. Billing to your Insurance would typically be for 57 unit doses of allergy extract for 1 kit or 114 units for 2 kits. ***Knowing this information will help you determine your costs based on your Insurance Policy Coverage.***

In addition, each time you receive a shot in our office, there is a small bill generated for a “Shot-administration fee”. Your maintenance vial refills (typically 20 shots of 0.5cc each) should last for 10 months. During a 3-year course of IT, you should expect to need about 3 or 4 maintenance refills.

Important: Before requesting that we mix an IT serum, you should call your Insurance Provider’s Customer Service Representative to review your specific contract agreement concerning fees related to Immunotherapy that you will be responsible for paying. Ask about any “**not covered**” services related to Allergy shots and inquire about any “**Co-pays**” for the shot administration fees (at each visit) and any “**Co-insurance**” (a percentage of the total cost

of the serum preparation that you may have to pay). You should also confirm that Michael P. Vaughn MD is an **“In-network”** medical provider for your specific policy because if we are “out-of-network”, you will be financially obligated to pay any Allergy service fees that may exceed the typical Insurance “allowable” payments that we bill.

If you are on an HMO, you may need a “Specialist” referral for Office-visit authorizations required during the 3-year process (typically once per year) and multiple recurrent authorizations for the allergy shots to be administered by our office (usually 50 or more the first year during “build-up” and then 24 per year during maintenance). If needed, ask your PCP for these referrals **before** requesting to start allergy shots. If your Medical Insurance deductible is high, and you doubt you will meet this amount during a 12-month period, you have the right to “opt-out” of your Insurance Plan and pay your costs as a **“Private pay”** fee; as this may be less expensive than using your insurance benefits. The down-side of using any private pay option is that your payments will not reduce your Medical Insurance Deductible. (A private pay fee schedule for Office visits, allergy shot administration and serum costs is available upon request from “Alamo Asthma & Allergy”, a medical practice solely owned and operated by Dr. Adrienne Vaughn).

Because Immunotherapy allergens are extremely expensive, we cannot mix your shots without a guarantee of payment. You will need to provide a credit card that can be used to pay any allergy serum preparation charge your Insurance determines that you will owe after our billing has been processed by them.

I agree to pay for my portion of the Insurance allowable charges for my IT preparation fee, as per my Medical Insurance Contract obligations, with a 1-time charge to my credit card:

Mastercard ___/ VISA ___/ Am. Exp. ___

Card # _____

Expires ___/___/___ Sec # _____

Signature: _____ Date ___/___/___

***A copy of this charge will be given to you immediately after processing when you visit for a shot administration (See our MA- Maggie)**

Amount Charged \$ _____ Date ___/___/___

Michael P. Vaughn PhD.MD.