

ALLERGEN IMMUNOTHERAPY (ALLERGY SHOTS) Information and Consent

What is Allergen Immunotherapy?

Allergen immunotherapy (AIT) or 'allergy shots' is a form of treatment prescribed for patients with allergic rhinitis (hay fever), allergic asthma or life threatening reactions to insect stings. It involves receiving regularly scheduled injections of purified extracts of allergens to which a person is allergic. Immunotherapy is the only medical treatment that could potentially modify allergic disease. It works by reducing sensitivity to allergens by gradual changes in the immune system. The result is that exposure to the offending allergen will cause fewer symptoms or no symptoms at all. Some studies have shown that it may have a preventive role in allergic children; possibly preventing asthma from developing in some kids with allergic rhinitis.

How effective is it?

Allergen Immunotherapy has been used for the treatment of allergies since around 1911. More than 100 years of experience has demonstrated its effectiveness for the treatment of respiratory allergies. Most patients on allergy shots notice improvement in symptoms and reduced use of allergy/asthma medications. This improvement is not immediate. It may take a few months to notice benefit and continuation of allergy shots leads to further improvement. The degree of benefit differs from person to person and is difficult to predict for an individual. For some patients the benefit lasts for several years after the treatment course. Although immunotherapy has been shown to significantly improve allergy symptoms, it is not considered a cure for allergies.

What is the procedure?

Allergy shots are customized to each patient. Each individual's allergen sensitivity is determined by allergy skin testing. The result of the skin test determines which allergens are included in the patient's allergy extract. Depending on the number of allergens to which a person is allergic, there may be one or two vials of extract requiring one or two injections, respectively, each time.

There are two phases to immunotherapy, Build-up phase and Maintenance phase –

Build-up: Allergy injections are started with a dilute extract and the dose is gradually increased with weekly or twice-a-week injections. With this schedule it may take 3-6 months to get to the maintenance dose. A more rapid build-up schedule, known as Cluster immunotherapy, is available. Maintenance may be reached in as little as 8 weeks with this schedule.

Maintenance: This phase begins when the effective therapeutic dose is reached. At this time the interval between shots can be increase to every 2-4 weeks. The maintenance dose and frequency of injections may be individualized based on response during the build-up phase.

How long are allergy shots given?

It is generally recommended that immunotherapy be continued for 3-5 years. At the end of this period the need to continue or stop the treatment will be reassessed. If numerous injections are missed during the treatment course, your doctor may discontinue your shots, since there is an increased risk of reactions under these circumstances.

Reactions to allergy shots

Allergic reactions can occur from immunotherapy itself. Reactions can be local (at the injection site) or systemic (affecting rest of the body).

Local reactions: These are more common and may consist of itching, redness or swelling at the injection site. It usually responds well to anti-histamines and cold compresses. Occasionally, large local reactions may occur



involving the entire arm and/or lasting more than 24 hours. Please let our nursing staff know, as this may require dosage adjustment.

Systemic reactions: These occur rarely, but have the potential to be serious. Systemic reactions may include hay fever like symptoms, flushing, hives, swelling, throat swelling, difficulty breathing, coughing, wheezing, dizziness, passing out. In more severe cases, anaphylactic shock may occur which can be fatal. The risk of systemic reactions is increased under certain circumstances such as uncontrolled asthma, severe allergy symptoms, heavy exposure to allergens during allergy season, and strenuous work-out right after an allergy injection.

Observation period after allergy injections

Allergy injections will be administered at a medical facility with a provider on duty on-site. All patients are required to wait in the clinic for *30 minutes after each injection*, due to the risk of serious allergic reactions. If you have had a systemic reaction to an allergy injection, you may be required to wait longer than 30 minutes. Please reschedule your allergy shot if you are unable to wait for the required amount of time. In the unlikely event of a systemic reaction, you will require prompt treatment to prevent worsening of the allergic reaction.

Pregnancy

Allergy shots may be continued during pregnancy. However, if you have not reached the maintenance dose, you will be continued on the current dose until after the pregnancy. If you become pregnant during immunotherapy, please let our staff know so that necessary dose adjustments can be made.

Medications

Certain medications ('Beta-blockers' used for high blood pressure, heart disease, migraine etc.) can increase the risk of serious allergic reactions from immunotherapy and should be avoided while on immunotherapy, if possible. If you are started on new medications while on immunotherapy, please let our staff know.

Cluster (Rapid) Immunotherapy

Cluster immunotherapy is a method of rapid desensitization that reduces the duration of build-up phase significantly, so that patients can get to their maintenance dose faster. It involves 3 (three) rapid desensitization visits, each lasting approximately 3 hours. During each of these visits patients get 4 (four) allergy injections 30 minutes apart. The interval between two rapid desensitization visits should be more than 48 hours, but no more than 7 days. After these three visits, patients get single dose every week until they reach maintenance dose. The risks of Cluster immunotherapy are the same as conventional immunotherapy and include both local as well as systemic reactions, as described above.

Instructions

The following steps will be taken for your safety while on immunotherapy –

- Immunotherapy will only be administered in the clinic with a provider on duty.
 - Always check your name and date of birth on the vial prior to each injection.
 - Report any current illness, especially allergy and asthma symptoms, to the nursing staff PRIOR to getting your allergy shot.
 - Your allergy shot will be rescheduled if you are having an asthma flare.
 - Report any new medications to the nursing staff PRIOR to your allergy shot.
 - Wait for at least 30 minutes in the clinic after every allergy injection.
 - Promptly report to nursing staff any symptoms of allergic reaction (see information above) that occur while waiting.
 - At the end of your waiting period check out with the nursing staff prior to leaving.
 - If you have a systemic reaction after you have left the clinic go to the nearest emergency medical facility.
 - Notify the nursing staff of any large local reactions.
 - Avoid strenuous physical activity for two hours following allergy shot to avoid the risk of a systemic reaction.
 - If you receive allergy injections twice a week during build-up, allow at least 48 hours between shots.
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- We recommend that you receive your allergy injections as scheduled. However, missing injections for a few weeks (due to illness or travel) is not a major concern. We will adjust your dosage, to reduce the risk of reactions, when you re-start the injections.
- Minors must be accompanied by a parent or an authorized adult guardian. Consent forms for the treatment of minors and authorization of accompanying adult guardians are available.

Please follow these instructions (in addition to the ones mentioned above) for your safety while on cluster immunotherapy –

- On the day prior to and the morning of the rapid desensitization take the following medications:
 - 1) Zyrtec 10mg OR Claritin 10mg OR Allegra 180mg once a day
 - 2) Zantac 150mg once a day
- Expect to be at the office for 3 – 3½ hours. Feel free to bring books, activities or your laptop with you.
- Wear comfortable clothes, preferably with short sleeves and bring a jacket in case you need it.





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Patient Name

DOB

_____ I have read the Allergen Immunotherapy Information and understand it. The opportunity has been provided for me to ask questions regarding the potential side effects of immunotherapy and these questions have been answered to my satisfaction. Reactions can include, but are not limited to, symptoms such as itching/hives/swelling, nausea/vomiting/diarrhea, runny nose, itchy/watery eyes, coughing/wheezing/difficulty breathing and loss of blood pressure/cardiac arrest/shock. Reactions, even though rare, can be severe and very rarely fatal. Delayed reactions may occur after leaving the office. I understand that every precaution consistent with the best medical practice will be carried out to protect against such reactions. I hereby give consent for the patient named above to receive allergen immunotherapy (allergy shots). I further agree that, if there is allergic reaction to the injections, providers at **Advanced Allergy & Asthma Associates** have permission to treat said reaction.

_____ I am authorizing the office to bill for allergen extracts, even if, for any reason, I decide not to initiate/continue allergen immunotherapy after the extract has been made. I understand that I am financially responsible for all co-pays, deductibles, co-insurance, non-covered services and unpaid services. I agree to obtain prior authorization, if needed, from my insurance plan.

_____ I understand the need to wait for 30 minutes in the office after each allergy injection, due to the risk of reactions

_____ I understand it is my responsibility to come to the office and get allergy shots regularly, as per my treatment plan.

Signature of Patient/Patient Representative

Date

Print Name

Relationship to patient

