

**ALLERGY, ASTHMA & CLINICAL IMMUNOLOGY SPECIALISTS, P.C.**

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**Immunotherapy- “Allergy Shots”**

Allergen immunotherapy (also known as “allergy shots”) is the repeated administration of specific allergens to patients with allergy-related conditions (such as insect allergy, hay fever and asthma) for the purpose of providing protection against their allergic symptoms and inflammatory reactions associated with exposure to these allergens. Immunotherapy should be used as part of a comprehensive allergy management plan that includes attempts to control allergy symptoms with appropriate environmental modifications and medical therapies. Immunotherapy is the only potential cure for allergic rhinitis and insect hypersensitivity. It is not a cure for asthma, but in those patients with asthma triggered significantly by allergens, it can result in improvement in the asthma as well. There is now also an FDA indication for atopic dermatitis.

Allergen immunotherapy has been practiced since the early part of the 20<sup>th</sup> century. Our understanding of how it works is constantly evolving, and although more is understood today than 80 years ago, the precise mechanism(s) for the observed clinical effects has yet to be determined. We do know that giving allergy shots modifies the patient’s immune system in such a way as to decrease sensitivity to the specific substances to which the individual is allergic. The following are theories that have been partially supported by clinical and scientific data.

- “Blocking Antibody”- The immune system responds to immunotherapy by producing a protein which binds with the allergen, blocking the allergy antibody from doing so, and thus not allowing an allergic reaction to occur.
- “Decrease in IgE (allergy antibody)”- Studies have shown that there is a gradual decrease (after an initial increase) in allergy antibody levels due to allergy shots.
- “Modulation of Cells That Play a Role in Allergic Reactions”- Immunotherapy decreases the release of certain chemicals from specific white blood cells. These chemicals would normally play a large role in the allergic reactions and would also “call in” other types of cells to the site of the allergic reaction. If left unchecked, these other types of cells would contribute to prolonging the allergic reaction.
- “Increase in Suppressor Cell Activity”- Some cells of the immune system are responsible for suppressing or controlling immunologic reactions. This is to prevent the reactions from actually damaging the host (patient). Allergy shots increase the activity of these suppressor cells.
- Several other mechanisms have been proposed and are also being studied.

**Types of Immunotherapy**

**Traditional Immunotherapy:** These injections begin at a very dilute concentration (to minimize the possibility of an allergic reaction) and gradually build up to maintenance level. Patients start by receiving 1 to 2 injections a week for about 9 months at a rate of one injection per week. Once maintenance levels have been obtained and maintained for a period of time, the frequency of injections is gradually tapered. Administration of high doses of allergen is the ultimate goal for this type of schedule. It may take 6 to 12 months to achieve this goal.

**Rush Immunotherapy (RIT):** We also provide rush immunotherapy for appropriate patients. This method involves the administration of several injections over the course of one day to reach maintenance levels in a brief period of time. The patient is evaluated in the clinic one week prior to RIT, and baseline lung function testing is performed. The patient is given pretreatment with antihistamines, prednisone, and leukotriene antagonists starting 3 days prior to RIT. The patient must be prepared to stay in the clinic from 8am-12pm and 1pm-5pm on the day of RIT. After the rush protocol is completed the patient will receive weekly injections for 8 weeks before starting to receive less frequent injections. The protocol has been demonstrated to be as safe and efficacious for insect allergy as standard protocols. However, there is a slight increase in frequency of adverse reactions when using pollens and house dust mites. These patients will see results from immunotherapy sooner than those who undergo traditional immunotherapy.

These techniques of immunotherapy have been scientifically studied and proven. There are other techniques that are still unproven. These include the administration of allergens sublingually (under the tongue) and neutralization-provocation therapy. These techniques are also different from the process of rapid desensitization, which is sometimes



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used in a controlled environment to prevent a reaction to a substance (such as penicillin) to which the patient is known to be allergic.

**Duration of Immunotherapy:** The optimal duration of immunotherapy for inhalant allergens has yet to be determined. For most patients that have a good response, 4 to 5 years of therapy is recommended by most allergists. Continuation of immunotherapy for 4 to 5 years is still recommended in patients who undergo rush immunotherapy despite more quickly reaching a maintenance dose. It is believed that benefit from a brief course of immunotherapy may be rapidly lost, whereas benefit from a longer course may persist after injections are discontinued. The time frame for a patient to respond varies from person to person. Some will notice a response within 6 to 8 months. Others may take up to 18 months to respond. In general, if there is not an adequate response by 2 years of therapy, the use of this treatment modality in that patient should be reassessed. In patients who have had a food response after 4 to 5 years of therapy, a trial period off of immunotherapy should be undertaken. A few patients will have an exacerbation of symptoms once the allergy shots have been discontinued. In these cases it may be desirable to continue the immunotherapy for a much longer period of time. These decisions must be made on a case-by-case basis.

Allergy shots for insect allergy may be safely discontinued after 5 to 7 years of therapy in many, but not all, patients, especially those sensitive to fire ants. This decision should be made on an individual basis.

### Conditions for Which Allergy Shot Have Been Shown to be Effective

- Allergic Rhinitis.

Also commonly known as hay fever, patients with this condition often suffer severe nasal (and possible eye and throat) reactions when exposed to pollens or other air borne allergens to which they are sensitive. Well designed scientific studies have been shown that immunotherapy is beneficial in the treatment of allergic rhinitis due to tree pollen, grass pollen, weed pollen, mold spores, dust mites, and animal allergens (e.g., cat and dog).

- Asthma.

Well-designed clinical studies have demonstrated the efficacy of allergen immunotherapy in patients with pollen-induced and mold-induced asthma. Some studies have also shown a benefit in patients with animal-induced or dust mite induced asthma.

- Insect Allergy.

Allergen immunotherapy should be considered in patients who have had reactions to insects after exposure to these allergens (such as through inhalation or injection). The efficacy of immunotherapy in patients allergic to the stings of honeybees, yellow jackets, hornets, wasps, and imported fire ants has been well documented.

- Atopic Dermatitis/Eczema

The FDA had recently approved the use of immunotherapy for atopic dermatitis/eczema.

### Conditions for Which Allergen Immunotherapy Has Not Proven Effective.

- Food Allergy

There are no well designed studies which have shown immunotherapy to be effective in patients with life threatening food allergy. However, this is an area of active research, and with time, this treatment modality may be available to patients with food allergies.

- Urticaria, and Candidal Infections

Thus far, the use of immunotherapy in these conditions remains unclear. The data that is available at this time is conflicting.

### Who Should Receive Allergy Shots?

Patients being considered for immunotherapy should undergo and appropriate evaluation by an allergist. This evaluation should include a clinical history correlated with specific allergens to which the patient is sensitive on allergy testing. Patients with allergic rhinitis, asthma, and/or insect sensitivity may be considered candidates. Factors to be taken into consideration when making this decision include severity and duration of symptoms (and the effect they have on the patients quality of life), and response to environmental avoidance measures and conventional medications. Unacceptable adverse reactions to conventional medications may also be taken into consideration. Other medical conditions the patient may have or other medications they may require can affect the decision making process.



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Patients who have completed immunotherapy in the past, but are again experiencing symptoms may require reevaluation with consideration for an additional course of immunotherapy.

Age of the patient plays a role in deciding whether to use immunotherapy or not. Most allergists do not recommend allergy shots for allergic rhinitis or asthma in children under 5 years of age. However, some studies have shown it to be effective in this age group and this decision should be individualized for each child. In fact there are studies supporting immunotherapy in younger children as a means of preventing the development of asthma and new allergic sensitivities. In children, (regardless of age) who have experienced life threatening allergic reactions to insect stings, the benefits of allergy shots may outweigh the risks. Most allergists do not recommend allergen immunotherapy for most patients over the age of 70. However, this too should be decided on a case-by-case basis based on the patient's prior history, co-existing medical conditions and response to conservative management of their allergies.

**\*\*The following should be read carefully\*\***

It is an explanation of the possible risks associated with immunotherapy (allergy shots) and will serve as an acknowledgement that you have been informed and understand that there may be adverse reactions to allergy shots. Included in the information below is a description of certain conditions that patients may have which may keep them from being candidates for allergy shots. Your signature in the appropriate place will also indicate that you do not currently have one of these conditions. We strongly advise you that is, in the future, you develop one of these conditions or are diagnosed with any new medical problem while you are on allergy shots, you can contact our office before the next injection to discuss this with us.

**Conditions Which May Prohibit Patients from Receiving Allergy Shots**

- Patients who are receiving a type of medication known as beta-adrenergic blocking agents should generally not receive allergen immunotherapy. This type of medication is often used to control high blood pressure, migraine headaches, certain types of tremor, and other medical conditions. A list of these medications is included with your instructional packet. If you are being treated for one of these conditions and are unsure if you are taking a beta-adrenergic-blocking agent, please discuss this with us. If one of these medications is prescribed for you after you begin allergy shots, you must contact us *before* your next injection. In rare circumstances, the decision to proceed with immunotherapy despite the use of these medicines may be made.
- Alternatives to allergen immunotherapy should be considered in patients with any of the following problems:
  1. Patients with markedly decreased lung function
  2. Patients with poorly controlled asthma
  3. Patients with unstable angina (chest pain related to heart conditions)
  4. Patients who have recently experienced a myocardial infarction ("heart attack") or significant arrhythmias (irregular heart rate and/or rhythm)
  5. Patients with uncontrolled hypertension (high blood pressure)
  6. Patients with failure of a major organ system (such as a kidney failure)
- Pregnancy will affect the management of immunotherapy. If you are now pregnant, please let us know before beginning allergy shots. If you become pregnant while taking allergy shots, you must let us know before your next injection.

**Adverse Reactions (Also Known As Risks) of Immunotherapy (Allergy Shots)**

The following is a description of the different types of reactions that may occur as a result of receiving allergy shots. It is important for you to realize that all forms of medical therapy, including allergy shots, can produce adverse reactions. There is always some degree of risk associated with medical therapies that must be weighed against the benefits to be obtained. **It is your responsibility to bring to our attention any problems that you may have as a result of your allergy injections.**



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**Local Reactions:** These reactions are defined as occurring in the immediate vicinity of the allergy injection site and are the most common type of reaction associated with allergy shots. These reactions can be classified by size and by the time it takes for them to develop. These reactions may consist of only localized pain, redness and swelling of various sizes. Large local reactions may involve the majority of the upper arm, extending up towards the shoulder and down to the elbow. These large reactions can be uncomfortable and adjustment of the extract dosage should be considered. Local reactions may occur within 20 or 30 minutes of the injection (during the period of time you are being observed in the doctor's office) or may develop several hours later and persist for a day or two. In general, these reactions are not serious and there is not a correlation between these reactions and the possibility of having a more serious systemic reaction (described below). If the reaction is unusually large or painful, you may need to call us for advice on symptomatic treatment of these reactions. In any case, please bring the occurrence of these reactions to our attention so that we may make any necessary adjustments in extract dosage.

**Systemic Reactions:** These reactions are defined as focal (involving one area of the body) or generalized (involving several areas of the body) symptoms occurring away from or distant from the site of injection. These reactions are more likely to occur during the build-up phase and in patients with asthma. However, they can occur at any time and in any patient. Symptoms that occur occasionally include hives (welts) and itching, hay fever-like symptoms (such as sneezing; nasal congestion and/or drainage; eye symptoms such as redness, itching, watering, and swelling of the eye lids), asthma symptoms (cough, shortness of breath, chest tightness, and/or wheeze) and are more serious than the local reactions described above. These symptoms should receive our immediate attention. **Again, if these occur, please notify us promptly of their development.**

Extremely rare systemic reactions that may occur include severe breathing difficulties (such as narrowing and spasm of the upper and/or lower airway); generalized hives accompanied by marked swelling of the face, hands, feet, tongue, throat, and/or genitalia; cardiac (heart) abnormalities (chest pain, irregular heart beat, sudden drops in blood pressure) and even death have been reported in association with allergy shots. The possibility of any of these types of reactions is extremely unlikely. In most instances, these types of reactions occur within 30 minutes of the allergy injection. It is for this reason that you are required to wait 30 minutes in the physician's office after receiving your injection.

**It is your responsibility to wait the appropriate period of time in the physician's office after each injection so that the doctor will be available to treat any serious adverse reactions that may occur.** In general, patients receiving injections for insect allergy must wait at least 30 minutes. All others must wait at least 20 minutes. Patients with extreme sensitivities or complaining medical conditions may be required to wait longer than these prescribed times.

**Allergy Shots Must Be Given In a Medical Facility**

This is the policy of our practice, and the vast majority of allergy practices in this country, that all allergy shots *must* be given a medical facility with a physician present who has been trained in the treatment of allergic reactions. This is for your protection. Although the risk of severe allergic reactions is very rare, the possibility that they may occur precludes us from allowing patients to administer injections to themselves or their children at home. Patients receiving injections for insect allergy must receive their injections in our office. This is due to the complexity of making up and administering these injections. All other injections may be given in our office or any physician's office that is convenient for you. Please indicate on the form below where you plan to receive your injections.

Patients receiving **Rush Immunotherapy** are at a slightly increased risk for systemic reaction, both during the day of the rush protocol and the next several weeks while the patient is on weekly injections. Patients are required to take the prescribed pretreatment medications for 3 days prior to the day of rush immunotherapy. Patients are required to stay in the office from 8am to 12pm and 1pm to 4pm on the day of rush immunotherapy. The patient will receive multiple injections at 30 minutes to one hour intervals throughout the course of the day with frequent clinical monitoring.



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Chart Number: \_\_\_\_\_

**Traditional Immunotherapy Patient Consent Form**

Immunotherapy, hyposensitization, or allergy injections should be administered at a medical facility with a medical physician present since occasional reactions may require immediate therapy. I am aware that these reactions may consist of any or all of the following symptoms: itchy eyes, nose, or throat; nasal congestion; runny nose; tightness in the throat or chest; coughing, increased wheezing; lightheadedness; faintness; nausea and vomiting; hives; and shock, the last under extreme conditions. Reactions, though unusual, can be serious but rarely fatal. I understand that I am required to wait in the medical facility in which I receive the injections for at least 30 minutes after I received each injection.

My signature below indicates that I have read the patient information sheets on immunotherapy and understand them. This signature also indicates my affirmation that I do not have any of the medical conditions described above as contraindications for immunotherapy. If one or more of these conditions is diagnosed by another physician while I am receiving immunotherapy, I will notify Dr. James and Dr. Raby's office before I receive any further allergy injections. The opportunity has been answered to my satisfaction. I understand that every precaution consistent with the best medical practice will be carried out to protect me against such reaction.

\_\_\_\_\_  
Patient Name D.O.B.

\_\_\_\_\_  
Patient Signature (Parent Signature if Patient Is a Minor Child) Today's Date

\_\_\_\_\_  
Witness Signature Today's Date

**Regarding Injections to Be Administered At an Outside Medical Facility**

Please complete the following if the allergy extract will be administered at an outside medical facility.

I have read all the information about allergy injections, and I agree that I will not attempt to administer my or my child's extract to myself or my child nor will I permit anyone who is not a licensed physician or under the supervision of a licensed physician to administer these extracts.

\_\_\_\_\_  
Patient Signature (Patient Signature is Patient Is a Minor Child) Today's Date

\_\_\_\_\_  
Witness Signature Today's Date

**FACILITY WHERE INJECTIONS WILL BE ADMINISTERED:**

\_\_\_\_\_  
Physician's Name Telephone

\_\_\_\_\_  
Office Address Fax Number

**The Allergy Shot Process and Understanding Your Financial Commitment**