Consent to Receive Immunotherapy (ALLERGY SHOTS)

Procedure

Allergy injections are usually started at a very low dose. This dose is gradually increased on a regular (usually 1-2 times per week) basis until a therapeutic dose (often called the ‘maintenance dose’) is reached. This dose may differ from person to person. Treatment is performed by a trained member of the medical staff and is given in the clinic.

Duration of Treatment

It usually takes 3-4 months to reach a maintenance dose. This time will be longer if there are reactions to the allergy shots or if the injections are not received on a regular basis. For this reason it is important that the recommended schedule be followed. Allergy injections may be discontinued if visits are frequently missed because there is an increased risk of reactions under these circumstances.

Immunotherapy Patient Consent

Immunotherapy, hypo sensitization, or allergy injections should be administered at a facility with a medical physician or his designate present as, occasionally, reactions may require immediate therapy. 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, wheezing, lightheadedness, faintness, nausea and vomiting, hives, generalized itching, and anaphylaxis, the last under extreme conditions. Reactions, even though unusual, can be serious but rarely fatal. Because of the risk, you are required to wait in the facility you received the injections for at least 20 minutes after each injection. Inform the staff at the facility if there is possibility that you might be pregnant. If you change medication or start a new medication (in particular, a blood pressure medication in the category of Beta-Blockers). Inform your physician or medical staff immediately if you are feeling ill, or have a fever or wheezing before an allergy injection is administered.

I have reviewed (if new patient) or re-read (if established) the patient information sheet on immunotherapy and understand it. The opportunity has been provided for me to ask questions regarding immunotherapy and these questions have 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 reactions.

Patient Payment: We recommend that each patient contact their insurance company to verify benefits for allergy injections. Some insurance companies require the patient to pay a co-pay for this service. The amount indicated below is based on what your insurance has informed us. However, this is not guaranteed until we receive an explanation of benefits. The patient has the final responsibility for all payments.

***PLEASE NOTE THAT PAYMENT IS DUE ON THE DATE OF SERVICE***

(95117)shot: ______________________
(95165)serum: ____________________

(Signature of Patient)

Date: ____________________________

(Signature of Patient or Guardian)

Date: ____________________________

(Witness)
Authorization to Prepare Allergy Serum

I authorize West Houston Allergy & Asthma, P.A. and its representative physician, P.A. to formulate my allergy serum for allergen immunotherapy (allergy injections). In most cases, the allergy serum will be prepared by the staff of West Houston Allergy & Asthma, P.A.

Patient’s Name (Please Print): ____________________________________________________

If I am receiving allergy injections at another facility I agree (or authorize the medical facility administering my injections) to re-order allergy serum at least two (2) weeks before starting a new vial.

Once authorization is received and allergy serum is prepared, the patient is responsible for full payment. If insurance is being filed, the patient will be responsible for any balance due. If you are seen for an office visit and receive an allergy injection in the same day, your insurance company may not pay for both services. In this event, the patient is responsible for payment of any balance due.

Patients without insurance and patients whose insurance does not cover allergy injections should contact our billing department for charges for serum and allergy injections.

I have read, understood and agreed with the information presented above.

_________________________________________________________ ____________________________
Signature of Patient (or Responsible Party if Patient is a Minor) (Date)

_________________________________________________________ ____________________________
(Signature of Witness) (Date)
Background Information about Immunotherapy
(Allergy Injections) For Patients

Facts Sheet: Efficacy and Safety of Immunotherapy
Immunotherapy, provided by qualified physicians, is an effective and safe treatment for asthma, allergic rhinitis and insect venom allergy.

Effective treatment for asthma
A meta-analysis of 20 published prospective studies showed that allergen immunotherapy is effective in the treatment of asthma. The American College of Allergy, Asthma & Immunology (ACAAI) recently compiled an annotated bibliography of 59 articles from the medical literature indicating the value of expert care immunotherapy for asthma. A meta-analysis of 23 published studies involving 935 asthmatic patients with documented allergy indicated that immunotherapy is effective in a selected population of allergic patients.

Effective treatment for allergic rhinitis
An extensive review of immunotherapy for allergic rhinitis in children showed that the only treatment able to affect the natural cause of the disease is immunotherapy, and that immunotherapy may prevent the onset of asthma. A meta-analysis of 18 published studies involving 789 patients concluded that immunotherapy is highly effective in the treatment of allergic rhinitis.

Effective treatment for insect venom allergy
Immunization with insect venom is an extremely effective treatment for preventing future systemic reactions to insect stings in individuals with previously demonstrated susceptibility. A meta-analysis of nine published studies indicated that a course of immunotherapy is highly effective in the management of insect sting hypersensitivity.

Immunotherapy Safety
A report from the Mayo Clinic on 79,593 immunotherapy injections over a 10-year period showed the incidence of adverse reactions to be less than two-tenths of percent (0.137 percent). Most of the reactions were mild and responded to immediate medical treatment. There were no fatalities.

More than 1 million injections were given without a fatality to 8,706 patients in allergy clinic at Roosevelt Hospital, New York City, between 1935 and 1955.

Comparative risks of immunotherapy
Nevertheless, rare occurrences of fatal anaphylactic episodes related to immunotherapy continue to be reported and studied. A total of 35 deaths following immunotherapy administration were reported for the year 1985 through 1993. It has been estimated that during that period there
were 52.3 million immunotherapy procedures, making the incidence of fatality less than one per million (0.6692 per million). Data compiled by the Allergen Products Manufacturers Association (APMA) estimates the incidence of fatalities to be about three per 190 million annual injections, or approximately one per 63 million injections. Another study evaluating 13 international fatalities related to immunotherapy between 1992 and 1996 identified an elevated risk for patients with active asthma and switched to high doses.

For perspective, it is useful to compare these statistics with the incidence of fatalities related to other kinds of injections. Studies of fatal anaphylaxis reactions to injected penicillin have ranged from 0.4 fatalities per million injections to one fatality per 7.5 million injections.

Fatalities related to radio-contrast “dyes” used in intravascular radiologic studies in the early 1980s varied from 1 in 13,000 procedures to 1 in 75,000 procedures. Other studies showed a substantial improvement to about one fatality in 169,000 procedures.

-Derived from the American College of Allergy, Asthma and Immunology.
Background Information about Immunotherapy (Allergy Injections) For Patients

Asthma can be defined as reversible airway disease. Outstanding symptoms may be bronchospasm or wheezing, cough, increased mucous production and chronic inflammation leading to airway obstruction. It is a very complex disease with many causes. While some patients only cough and wheeze when they have an upper respiratory infection, others may wheeze when they exercise, hyperventilate or breathe cold air.

Patients who have asthma attacks when taking aspirin or other non-steroidal anti-inflammatory drugs (like ibuprofen) have an abnormal release of leukotrienes, one of the body’s asthma-producing chemicals. Inhaling an allergen triggers the most common form of asthma. Thus someone with an allergy to cats may start to wheeze when walking into a home with a cat. The small amount of cat protein in the air will excite the allergy response even before the person knows there is cat in the home. Likewise, exposure to plant pollens, dust mites, mold, latex, and other protein substances can evoke an asthma attack in susceptible individuals.

Immunotherapy has been used to treat allergic rhinitis (“allergies or hay fever”) for almost a century. Charles Blackley first attempted desensitization on himself to treat his “hay fever” in 1873. By 1911 Dr. Leonard Noon had published a system of immunotherapy, or allergy shots.

In addition, many allergists have used immunotherapy to treat asthma. However, there have been arguments over the effectiveness of this therapy. This disagreement has led to extensive studies to prove or disprove the therapy.

International conferences in Paris and New York have addressed the treatment of asthma with immunotherapy. The World Health Organization published a position paper in 1998 on “Allergen Immunotherapy: Therapeutic Vaccines for Allergic Disease.” Several well-done studies were reviewed that demonstrated improvement in asthma with immunotherapy. Therapy with allergy vaccines for pollens, cat and dog antigens may even prevent the development of asthma in susceptible individuals.

Immunotherapy treatment can be highly effective when the major cause of asthma is an inhaled allergen that cannot be avoided. Treatment early in the course of the disease can prevent the development of more severe asthma. Allergists can help you by performing a detailed history and exam and by testing you to see if you have the type of asthma that might respond to allergy shots. There are many medications that can help asthma, but asthma relapses occur when people stop taking medication. Immunotherapy is the only therapy that can give long-lasting relief.

Information derived from the American College of Allergy, Asthma and Immunology.
Background Information about Immunotherapy
(Allergy Injections) For Patients

Allergy Shots

Depending on the severity and nature of your allergies, allergen avoidance and allergy medications alone may not effectively manage your symptoms. You may need to identify and address the root causes of your condition instead of simply treating your symptoms.

Allergy shots (also known as immunotherapy or desensitization) currently is the most effective form of treating the underlying allergic mechanism that causes allergic conditions such as allergic rhinitis (hay fever), allergic conjunctivitis, allergic asthma, and allergies to insect stings. At the present time, however, immunotherapy does not provide a safe effective treatment for food allergies.

Does immunotherapy make sense for you?

Immunotherapy may be appropriate for treating your allergies, depending on the following factors:

- Effectively avoiding allergens that trigger your allergies is impractical, or even impossible, because the life you lead inevitably results in allergen exposure.
- Your allergy symptoms are consistently severe or debilitating.
- Managing your allergy symptoms requires prohibitively expensive medication courses, which produce side effects that adversely affect your overall health and quality of life. If the health and financial costs of allergy drugs outweigh their benefits, immunotherapy may make more sense for you.
- Allergy testing provides conclusive evidence of specific IgE antibodies, thus allowing allergists to diagnose the specific allergenic cause of your ailment, and appropriate allergen extracts are available.
- You haven’t experienced serious adverse side effects, as a result of skin testing, to the allergens that your doctor will use in your subsequent course of immunotherapy.
- You can make the commitment to see the therapy process through. Immunotherapy isn’t a quick fix, and it requires a significant investment of your time.
- If you suffer from an unstable heart condition and you take beta-blockers such as Inderal or if you take monoamine oxidase (MAO) inhibitors, don’t consider immunotherapy unless your physician advises you that the benefits of starting immunotherapy outweigh the risks of discontinuing those medications.

Information derived from the American College of Allergy, Asthma and Immunology.