

ADMINISTRATION OF ENVIRONMENTAL IMMUNOTHERAPY (Allergy Injections)

Please read and be certain that you understand the following information prior to signing the Environmental Immunotherapy Patient Consent

PURPOSE

The purpose of immunotherapy (allergy injections) is to decrease your sensitivity to allergy causing substances so that exposure to the offending allergen (pollen, mold, mites, animal danders, etc.) will result in fewer and less severe symptoms. This does not mean that immunotherapy is a substitute for avoidance of known allergens or for the use of allergy medications, but rather is a supplement to those treatment measures.

Allergy injections have been shown to lead to the formation of “blocking” or protective antibodies and a gradual decrease in allergic antibody levels. These changes may permit you to tolerate exposure to the allergen with fewer symptoms. You, in effect, become “immune” to the allergen. The amount of this immunization is different for each person and is therefore somewhat unpredictable.

INDICATIONS

To qualify for immunotherapy, there must be a documented allergy to substances in the environment that cannot be avoided. Documentation of allergy can be either in the form of a positive skin test or a positive blood test. In addition to demonstrable allergy by one of the above tests, problems such as hayfever or asthma should occur upon exposure to the suspected allergen. Due to the inherent risks of immunotherapy, avoidance measures and medical management should usually be attempted first.

EFFICACY

Improvement in your symptoms will not be immediate. It usually requires 3 to 6 months before any relief of allergy symptoms is noted, and it may take 12 to 24 months for full benefits to be evident. About **75-80%** of allergic patients on immunotherapy note significant improvement of their symptoms. This means that symptoms are reduced, although not always completely eliminated.

PROCEDURE

Allergy injections contain things you are allergic to and are usually begun at a very low dose. This vaccine dosage is gradually increased on a regular basis until a therapeutic dose (often called the “maintenance dose”) is reached. The maintenance dose will differ from person to person. Injections typically are given once or twice per week while the vaccine dose is being increased. This frequency reduces the chances of a reaction and permits the maintenance dose to be reached within a reasonable amount of time. After the maintenance dose is determined, the injections can usually be given every 4 to 6 weeks. When new serum for your vaccine is mixed, your dose is decreased and a minimum of three weekly injections are required. This usually occurs 1 to 2 times per year.

DURATION OF TREATMENT

It usually takes a minimum of 6 to 12 months to reach a maintenance dose. The time may be longer if there are reactions or if the injections are not received on a regular basis. For this reason, it is important that the recommended schedule be followed. **If you anticipate that regular injections cannot be maintained, immunotherapy should not be started.**

Immunotherapy may be discontinued at the discretion of Dr. Edmondson or Dr. Hostetler if the injections are frequently missed, as there is an increased risk of reactions under these circumstances. Most immunotherapy patients continue treatment for five years once they reach their maintenance dose. The need for continuation is reassessed on a yearly basis as is your progress, symptoms, need for medications and reactions. All immunotherapy patients are required to have at least yearly follow-up with Dr. Edmondson or Dr. Hostetler. Patients with asthma may be required to have follow-up appointments every 3 to 6 months.

ADVERSE REACTIONS

Immunotherapy is associated with some recognized risks. Risk is present because a substance to which you are known to be allergic is being injected into you. A few adverse reactions may be life-threatening and may require immediate medical attention. **You will be required to bring an epinephrine auto-injector to all injection appointments.** In order of increasing severity, the following brief descriptions explain the nature of these potential reactions:

A. LOCAL REACTIONS

Local reactions are common and are usually restricted to a small area around the site of the injection. However, they may involve a larger area, with varying degrees of redness, swelling, pain and itching. These reactions are more likely to occur as you reach the higher concentrations and higher volumes of vaccine. The reactions may occur several hours after the injection. You should notify medical personnel if your local reaction exceeds two inches in diameter or lasts until the following day. Vaccine dosage adjustment may be required for large or uncomfortable local reactions.

B. GENERALIZED REACTIONS

Generalized reactions occur rarely, but are the most important because of the potential danger of progression to loss of consciousness and death if not treated. These reactions may include:

1. **Urticarial reactions (hives)** include varying degrees of rash, swelling, and/or itching. There may be mild to moderate discomfort, primarily from the itching. This uncommon reaction may occur within minutes to hours after an injection.

2. **Angioedema** is rare and is characterized by swelling of any part of the body, internally or externally; such as the ears, tongue, lips, throat, intestine, hands or feet, alone or in any combination. This may occasionally be accompanied by asthma and may progress to the most severe reaction, anaphylactic shock. In the absence of shock, the principle danger lies in suffocation due to swelling of the airway. Angioedema may occur within minutes after the injection and requires immediate medical attention.

3. **Asthma** may occur acutely with shortness of breath and wheezing. It may need immediate treatment to prevent acute respiratory distress.

4. **Anaphylactic shock** is the rarest complication, but is a serious event characterized by acute asthma, vascular collapse (low blood pressure), unconsciousness, and potentially death. This reaction usually occurs within minutes of the injection and is extremely rare.

The above reactions are unpredictable and may occur with the first injection or after a long series of injections, with no previous warning. All generalized reactions require **immediate evaluation and medical intervention.** If a generalized reaction occurs, the vaccine dosage will be adjusted for subsequent injections. Further allergy injections will not be administered until a follow-up appointment with Dr. Edmondson or Dr. Hostetler is completed.

OBSERVATION PERIOD FOLLOWING INJECTIONS

All patients receiving immunotherapy injections are required to wait in the clinic area for **30 minutes following each injection.** If you have a reaction, you may be advised to remain in the clinic longer for medical observation and treatment. If a generalized reaction occurs after you have left the clinic area, you should **immediately return to the clinic or go to the nearest emergency medical facility.** If you cannot wait the 30 minutes after your injection, you should not receive an immunotherapy injection. It is estimated that of the approximately 10 million allergy injections administered each year in the United States there are several allergy vaccine related deaths. While most systemic reactions are not life-threatening if treated promptly, this fact does stress the importance of remaining in the clinic for the suggested observation time. If you do not remain in the clinic area for the designated time, the doctor may recommend discontinuation of immunotherapy.

ADMINISTRATION OF IMMUNOTHERAPY AT AN OUTSIDE FACILITY

Under no circumstances will injections be permitted without the immediate availability of emergency medical treatment. If the prescribed injections are to be given elsewhere, our clinic must be provided with the name and address of the physician who will assume the responsibility for your injections. It is your responsibility to find the appropriate outside medical facility willing to administer your allergy injections. The provider of the outside medical facility is required to sign a consent. We must have this consent on file before your vaccine will be sent to the outside facility.

EXERCISE OR STRENUOUS ACTIVITY

No exercise or strenuous activities are allowed for one hour prior or two hours following injections.

INITIAL EXTRACT PRESCRIPTION

Your initial prescription includes all vaccine vials that are required to reach a “maintenance” dose. In order to utilize these vials prior to their expiration date, you will need to receive injections 1 to 2 times per week on a regular basis.

PREGNANCY

Females of child-bearing potential: If you become pregnant while on immunotherapy, notify the office staff immediately so that Dr. Edmondson or Dr. Hostetler can determine an appropriate dosage schedule for the injections during pregnancy. Immunotherapy doses will not be advanced during pregnancy, but may be maintained at a constant level, and the interval of injections may be increased to monthly. Furthermore, immunotherapy will **never** be started during a pregnancy.

NEW MEDICATIONS

Please notify the medical staff if you start any new prescription medications, particularly medication for high blood pressure, migraine headaches, and glaucoma. Beta blocker medications are inadvisable while on immunotherapy, and your injections may need to be discontinued while you are taking a beta blocker.

ALLERGY INJECTION SCHEDULE

Allergy injections are offered in our office on a scheduled basis by appointment. A minimum 48 hour interval is necessary between injection visits. A parent or legal guardian must be present before an injection will be given to a minor. Children age 16 years and older may be allowed to receive their injections unaccompanied with signed permission from their parent or legal guardian.

FINANCIAL POLICY

It is the patient’s responsibility to provide up to date insurance information, and balances need to be current at the time of remixing serum. If you choose to discontinue allergy injections, you will still be responsible for any prior balances incurred.