

Mala Bathija MD, PLLC

44000 West 12 Mile Road, Suite 212
Novi, MI 48377

14500 Northline Road
Southgate, MI 48195

Consent for Administration of Immunotherapy (Allergy injections)

Please read and be certain that you understand the following information prior to signing this consent for treatment

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 dander, stinging insects, 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 is rather 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 documented allergy to substances in the environment that can not 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, or you may have a history of a severe reaction to an insect sting. Due to the inherent risks of immunotherapy, avoidance measures and medical management should usually be attempted first.

EFFICACY

Improvement in you symptoms will not be immediate. It usually requires *6 to 12 months* before any relief of allergy symptoms is noted, and it may take 12 to 24 months for full benefits to be evident. About 85-90% 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 are usually begun at a very low dose. This dosage is gradually increased on a regular basis (usually 1 time per week) until a therapeutic dose (often called the “maintenance dose”) is reached. The maintenance dose will differ from person to person. Injections are typically given once per week while the vaccine dose is being increased. This frequency reduces the chances that 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 one to four weeks.

DURATION OF TREATMENT

It usually takes three to six months to reach a maintenance dose. The time may be longer if there are vaccine 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. Bathija if the injections are frequently missed, as there is increased risk of reactions under these circumstances. Most immunotherapy patients continue treatment for 3-5 years, after which the need for continuation is reassessed. Discontinuation of therapy earlier than 3-5 years may result in a higher increase of recurrence

ADVERSE REACTIONS

Immunotherapy is associated with some widely recognized risks. Risk is present because a substance to which you are known to be allergic is being injected into you. Some adverse reactions may be life-threatening and may require **immediate medical attention**. 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 the entire upper arm, with varying degrees of redness, swelling, pain, and itching. These reactions are more likely to occur as you reach the higher concentrations and higher volume injections. These reactions may occur several hours after the injection. You should notify us if your local reaction exceeds two inches in diameter or lasts until the following day.

B. GENERALIZED REACTIONS:

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

- (1) **Nasal congestion, runny nose, sneezing**
- (1) **Urticarial reactions (hives)** include varying degrees of rash, swelling, and/or itching of more than one part of the body. 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 characterized by swelling of any part of the body, inside or out, 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) **Anaphylactic shock** is the rarest complication, but is a serious event characterized by acute asthma, vomiting, diarrhea, 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 and you must see Dr. Bathija before your next injection.** If a localized or generalized reaction occurs, the vaccine dosage will be adjusted for subsequent injections.

Appropriate advice and treatment will always be available from our office staff at the time of any adverse reaction.

OBSERVATION PERIOD FOLLOWING INJECTIONS

All patients receiving immunotherapy injections should wait in the clinic area **for 30 minutes following injection**. If you have a reaction, you may be advised to remain in the clinic for longer for medical observation and treatment. If a generalized reaction occurs after you have left the clinic area, you should immediately return to the medical 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. There are several allergy vaccine-related deaths each year in the United States. While most systemic reactions are not life-threatening if treated promptly, this fact stresses 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.

INITIAL EXTRACT PREPARATION

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 (6 months from the date of preparation), you will need to receive injections once a week on a regular basis. If you take injections once per week regularly, you will reach maintenance level at about the same time as the expiration date. When you receive regular maintenance injections, the renewal vials generally last 2-3 months, but still carry a 6-month expiration period.

PREGNANCY

Females of child-bearing potential: If you become pregnant while on immunotherapy, notify the office staff immediately, so that Dr. Bathija 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.

NEW MEDICATIONS

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

ILLNESS

If you are having any symptoms or are sick, please schedule an appointment to see your doctor before receiving an injection. If you are feeling well, you may receive your injections without waiting to see the doctor. However, we would like to have you see a doctor each time you start new vials.

EPIPEN

At the start of immunotherapy, you will be prescribed an Epipen (injectable epinephrine) for use in the event of a generalized reaction to immunotherapy. This is to be used should a reaction occur after the 30 minute waiting period proceeding your allergy injection. You will be instructed on the use of this emergency medication and should go to the nearest emergency room after its use. You will need to have this with you at the time of your allergy injection, otherwise the injection will be withheld for that day.

APPOINTMENTS

Allergy injections will be administered by appointment only.

ATTACHMENTS

I acknowledge that I have received the following attachments on immunotherapy entitled:

- (1) Tips to Remember: What are "Allergy Shots?"
- (2) Getting a Jump Start on Your Immunotherapy Treatment
- (3) Medications to avoid while on immunotherapy
- (4) Epipen information

Consent for Administration of Immunotherapy (Allergy Injections)
Authorization for Treatment

I have read the information in this consent form and understand it. The opportunity has been provided for me to ask questions regarding the potential risks of immunotherapy, and these questions have been answered to my satisfaction. I understand that precautions consistent with the best medical practice will be carried out to protect me from adverse reactions to immunotherapy. I do hereby give consent for the patient designated below to be given immunotherapy (allergy injections) over an extended period of time and at specified intervals, as prescribed by Malathi Bathija MD. I further hereby give authorization and consent for treatment, by Dr. Bathija and her staff, of any reactions that may occur as a result of an immunotherapy injection.

Printed name of immunotherapy patient

Patient signature (or legal guardian)

Date signed

Witness

Date signed