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IMMUNOTHERAPY GUIDELINES AND CONSENT

*****PLEASE READ AND BE CERTAIN THAT YOU UNDERSTAND THE FOLLOWING INFORMATION PRIOR TO SIGNING THIS CONSENT FOR TREATMENT**

PURPOSE:

The purpose of subcutaneous immunotherapy (allergy injections) is to decrease your sensitivity to allergy-causing substances, so that exposure to the offending allergen (pollen, mold, mites, animal danders, stinging insects, etc.) will result in fewer and less severe symptoms. This does not mean that allergy injections are 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 an alteration of your immune system's response to naturally occurring allergens. These alterations 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 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 positive allergy tests, problems such as rhinitis 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 be attempted first.

EFFICACY:

Improvement in your symptoms will not be immediate. It usually requires 3 to 6 months before relief of allergy symptoms is noted, and it may take 6-12 months for full benefits to be evident. The majority of patients on subcutaneous immunotherapy note significant improvement of symptoms within the first year of maintenance injections. This means that symptoms are reduced, although not always completely eliminated.

PROCEDURE:

Allergy injections are usually started at a very low dose. The dosage is gradually increased on a regular basis (1-2 times per week) until a therapeutic (maintenance) dose is reached. The Maintenance dose will differ from person to person. Injections typically are given once or twice per week while the dose is being increased. This frequency reduces the chance of a reaction and permits that the maintenance dose be reached within a reasonable amount of time. After the maintenance dose is reached, the injections may be given every two weeks.

DURATION OF TREATMENT:

It usually takes 3 to 6 months to reach a maintenance dose. The time may be extended if there are any reactions to the injections or if injections are not received on a regular basis. Therefore, it is important that the recommended schedule be followed. If you anticipate that regular injections cannot be maintained, immunotherapy should not be initiated. Immunotherapy may be discontinued at the discretion of the doctor if the injections are frequently missed, as there is an increased risk of adverse reactions under these circumstances. Most immunotherapy patients continue treatment for 3-5 years, typically at increasing intervals. A follow-up visit with the doctor should be scheduled at least once per year for a re-evaluation of allergy symptoms.

ADVERSE REACTIONS:

Allergen immunotherapy is associated with occasional adverse reactions. Risk is present because a substance to which you are known to be allergic to is being administered to you. Some adverse reactions may be life-threatening and may require immediate medical attention. Potential adverse reactions include, but are not limited to, the following (listed in order of increasing severity):

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 may occur several hours after the injections. You should notify the injection nurse prior to your next injection if your local reaction exceeds two inches in diameter or lasts beyond 24 hours.

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) **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 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, 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 an asthma exacerbation 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, vascular collapse (low blood pressure), unconsciousness, and potentially death. This reaction is rare and usually occurs within minutes of the injection; however, there are reported cases of anaphylaxis beginning as long as 2 hours after an injection.

OBSERVATION PERIOD FOLLOWING INJECTIONS:

All patients receiving immunotherapy injections should wait in the office for at least 30 minutes following each injection, or longer if it is advised to remain in the office for continued medical observation and treatment. If a generalized reaction ever occurs after you have left the office you should return to the office, go to the nearest emergency medical facility, or call 911. According to the most recent National Guidelines, most serious systemic reactions from Allergen Immunotherapy occur within 30 minutes after an injection, and patients should remain in the physician's office for at least 30 minutes after allergy immunotherapy injections. While most systemic reactions are not life-threatening if treated properly, there have been immunotherapy-related deaths, therefore it is important to remain in the office for the required observation time.

ALTERNATIVES TO ALLERGY INJECTIONS:

Patients have two alternative approaches to their allergy treatment: 1) avoidance of recognized environmental allergens and 2) medications for symptom control. The discussion with the physician has outlined the "pros and cons" of each approach, as well as the option of no specific treatment.

INITIAL SERUM PREPARATION:

Your initial preparation of serum includes all 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 at least once or twice per week on a regular basis. Taking injections twice per week will allow you to reach maintenance earlier, well before the expiration date. If you take injections once per week regularly, you should still reach maintenance level before the date of expiration. When you receive regular maintenance injections, the renewal vials generally last 3-4 months, but then carry a 1-year expiration period.

PREGNANCY:

Females of child-bearing potential: If you become pregnant while on immunotherapy, notify the office staff immediately, so the doctor can determine an appropriate dosage schedule for the injections during pregnancy. Immunotherapy doses will be maintained at a constant level and will not be advanced during pregnancy.

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 may need to be discontinued while you are taking a beta blocker.

ALLERGY INJECTION SCHEDULING:

There are printed schedules at the front desk that should be filled out with your desired times for injections. These times are flexible, and you are welcome to call to change your scheduled time, and it is allowable for you to come at a different time on your scheduled day as long as it is in the times listed that we are giving injections. We will do everything possible to make it convenient for you to receive your injections in a timely manner. Injections may be done no more than twice weekly and there must be at least 48 hours in between injection visits.

GENERAL GUIDELINES TO REMEMBER:

- 1) Try not to rub or scratch the injection site as this may cause an increased local reaction. Upon request, we have spray or cream that helps with itching at the injection site, and ice that may help alleviate pain and swelling.
- 2) Normal reactions at the injection site are characterized by localized redness, itching, swelling, and welts up to a half-dollar size. It is helpful to take an antihistamine one hour prior to your injections, if possible, to help reduce both local and systemic reactions to your injections. Ice, elevation, and Ibuprofen will also help relieve local reactions. Please notify the office staff immediately if any of the above symptoms have increased and become uncomfortable or you have experienced any systemic reaction symptoms to your injections, as we may need to adjust the dose of your injections.
- 3) Please do not take part in any strenuous physical activity for at least 2 hours following your injections, as this could increase your risk of developing an allergic reaction to your injections.
- 4) Your injections should not be given if you are ill. Please notify the office staff prior to your injections if you have had a temperature greater than 100.5 degrees, have an acute cough, colored drainage, or have wheezing or tightness in your chest. We normally have appointments available for you to be evaluated by the doctor or a physicians assistant within 48 hours if desired.
- 5) For the comfort of our patients with allergies and/or asthma, please refrain from wearing perfume, aftershave, or cologne into our office for your appointments

**CONSENT FOR ADMINISTRATION OF ALLERGY IMMUNOTHERAPY/
AUTHORIZATION FOR TREATMENT**

I HAVE READ AND UNDERSTAND THE INFORMATION IN THIS CONSENT FORM. THE OPPORTUNITY HAS BEEN PROVIDED FOR ME TO ASK QUESTIONS REGARDING THE POTENTIAL RISKS OF ALLERGY IMMUNOTHERAPY, AND EACH QUESTION HAS 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 ALLERGY INJECTIONS OVER AN EXTENDED PERIOD OF TIME AND AT SPECIFIED INTERVALS, AS PRESCRIBED BY THE PHYSICIANS AT BAYSIDE ALLERGY. I FURTHER HEREBY GIVE AUTHORIZATION AND CONSENT FOR TREATMENT, BY THE PROVIDERS AND/OR STAFF OF BAYSIDE ALLERGY, OF ANY REACTIONS THAT MAY OCCUR AS A RESULT OF AN IMMUNOTHERAPY INJECTIONS. (By signing below, I am also giving consent for the above injections or treatments to be given by Bayside Allergy staff without a parent or legal guardian present.)

Printed Name of Patient: _____ DOB: _____

Signature of Patient (or Legal Guardian): _____ Date: _____