



## What is immunotherapy?

Immunotherapy is a scientifically accepted form of treatment for allergic disorders. The treatment involves the subcutaneous injection of very small doses of allergen, to which the patient is allergic. When these injections are repeated, the body builds resistance or immunity to the injected allergens. Many carefully performed studies have shown the effectiveness of immunotherapy for decreasing symptoms.

During a course of immunotherapy small doses are injected and the dose is gradually increased each week. The slow build-up of the allergen dose decreases the possibility of the injection itself causing an allergic reaction. Injections are usually given once or twice a week, until a maintenance dose is reached, which can require up to one year. The time it takes to reach maintenance may be longer if an individual has problems tolerating the injections or if injections are not received on a regular basis. After the maintenance or therapeutic dose is reached, then longer intervals between injections are instituted. The maintenance dose can vary from person to person.

### Potential Benefits

The clinical response to immunotherapy varies from individual to individual, but on average, clinical benefit can be expected in approximately 80% of patients who receive this form of treatment. This means, less or no use of allergy medications and reduced allergic symptoms. We therefore feel that if medications are ineffective or are associated with unacceptable side effects, or cost, then immunotherapy should be considered as a treatment alternative.

Patients who respond to immunotherapy usually gradually improve during the course of treatment. Symptoms may begin to improve following six months of therapy, but occasionally 12-18 months of treatment may be required before improvement is noted. There are no blood tests or skin tests that prove that immunotherapy is working. Improvement is based solely on clinically following a patient's symptoms during a course of immunotherapy. If the maximum response is obtained, then allergy injections may be discontinued. Some patients may have a return of their symptoms months or years after stopping allergy injections, but there is no way to identify those patients who will relapse or require additional treatment.

### Possible Side Effects

There are two types of adverse reactions which may occur after an allergy injection. The most common type is a local reaction. These vary from small red, raised areas at the injection site to larger areas that may be swollen, warm, tender and itchy. These local reactions are usually managed by taking an antihistamine and applying an ice pack and a topical anti itch medication to the injection site. Please notify the nurse so your next dose can be decreased.

The second type of reaction is a generalized or systemic reaction. Less than 0.1% of individuals receiving shots have a generalized reaction. These reactions are rare, however, they may occur at anytime, even if the individual has tolerated allergy injections for months or even years. These reactions can consist of hives, wheezing, throat swelling, low blood pressure with loss of consciousness and even death. There are, on average, several allergy shot related deaths per year in the United States. Generalized reactions usually promptly respond to an injection of adrenaline, but sometimes additional therapy is required to treat the reaction. This is why it is essential to always receive allergy injections in a doctor's office so you can be treated promptly and appropriately in the event of a reaction. Since the majority of generalized reactions occur within 20-30 minutes after the injection, ***we require all patients to remain in the Doctor's office for at least 20 minutes after every injection.*** There can be no exceptions to this 20 minute waiting period. If you leave one of our offices before the 20 minute waiting period is up, a warning will be given. After two episodes of leaving early, you will no longer be permitted to receive allergy injections at the Center for Ear, Nose, Throat & Allergy.

After you have read and signed this consent form and we have received an order to begin shots from your physician, your first batch of serum will be mixed and your account will be billed accordingly. We ask that you receive your first injection of the new serum at one of our offices. This is necessary because there may be a difference in the allergen content of the new serum and therefore an increased risk for a reaction. After your first injection, you may take the allergy serum to another Physician's office if this is more convenient for you. The serum will come with written instructions and a specific injection schedule for the Doctor's office to follow. We require that the physician supervising your injections write a note on a prescription pad stating that they agree to administer the injections and are equipped to treat a reaction. **The serum does require refrigeration.** In order to continue to receiving allergy serum, you must be seen by one of our Doctors annually or we reserve the right to refuse to refill your allergy serum. The immunotherapy program can be canceled at anytime by submitting written notification to the Center for Ear, Nose, Throat & Allergy. Female patients are responsible for notifying our office immediately if they are pregnant.

## Information for Allergy shots

### **Hours, Locations and Schedules:**

- **North:** Mon 1-5 pm, Tues 1-5:30 pm, Fridays 7:45 -11 am      **Avon:** Mon1-5pm, Thurs , 8-11 am & 1-5pm
- The patient will be getting weekly injections while working up to a maintenance dose (maximum tolerated strength). Then they will continue to come in weekly for a year from the date they started on maintenance.
- 1-1 1/2 years = weekly, 2<sup>nd</sup> year = every 2 weeks, 3<sup>rd</sup> year = every 3 weeks, and possible a 4<sup>th</sup> year = every 4 weeks. The entire program can last anywhere from 3-5 years. The physician will make schedule changes based on symptom control & length of time on maintenance.
- If the patient misses an injection they may come twice in one week to make up for it, with a minimum of **48 hours** in between.
- Your doctor will monitor your progress throughout your treatment. Follow up visits should take place 3 months, 6 months, and one year into your treatment. After that, you will need to see your doctor at least once a year while on allergy shots. We reserve the right to hold the serum if an annual appointment is not made. **A 30 day, written notice must be given to the Allergy Department, if you decide to discontinue your injections.**

### **Guidelines**

- The patient needs to inform the nurse of any changes with their medications. Beta blockers complicate the treatment of a systemic reaction and therefore are contraindicated while on Immunotherapy.
- The patient should avoid any other type of injections within 48 hours of their allergy shot. (ex, flu shot, pneumonia shot)
- If a patient is having an increase in asthma symptoms (ex. shortness of breath, wheezing), has a rash or hives or is running a fever above 100 degrees, no injection should be given that day.
- The patient should avoid any type of exertion 2-3 hours before and after their shot.
- Each patient is required to **wait 20 minutes in the office after every injection, even if the patient is on a maintenance dose. We reserve the right to refuse the injection if a patient does not wait.** At the end of the 20 min wait, the patient must return to show the nurse the injection site so we can document any reaction.
- For females, if there is a chance that you are **pregnant**, please notify the nurse immediately.

### **Costs**

- The cost of your vial is dependant on how many injections you are scheduled to receive from each vial. The cost of the serum is \$18 per injection or unit. For example, a vial designed for 6 injections would be \$108, or a vial designed for 10 injections would be \$180. This will vary as you progress through the treatment program. The cost to administer a single injection is \$20 or \$26 for multiple.
- The serum expires in 12 weeks. If the patient does not progress through the entire vial due to noncompliance with their treatment schedule, a remixing fee of \$25 will be billed directly to the patient.
- We recommend that the patient call their insurance company to verify coverage and to obtain the benefits for allergy shots and the serum. The insurance company may ask you for CPT codes (procedure codes) : serum 95165, injections-95117
- Serum is remixed about 2 weeks before the expiration date. Each time new serum needs to be made, your account balance will be checked. If you have an outstanding balance on your account of \$50 or more, the mixing of your serum may be put on hold until a payment is made.

### **Reactions:**

- From time to time the patient may experience local reactions (redness, swelling and itching) after an allergy injection. Applying an ice pack, a topical anti-itch medication or taking an antihistamine will help. Antihistamines can be taken prior to receiving an allergy injection if the patient experiences local reactions or an increase in symptoms after getting their injections.
- Each week during the escalating phase, we will increase the dose if no reaction occurs. It is imperative that the patient communicate any problems (such as swelling around the injection site or an increase in allergy symptoms) to the nurse BEFORE the next injection is given, so a dosage adjustment can be made. We need to know about any reaction on the arm that is larger than the size of a quarter or that lasts more than 48 hours.
- Although we take precautions to prevent reactions, there is a chance that an anaphylactic reaction can occur. Signs of a severe reaction can include but are not limited to: tightening in the chest , tongue or throat swelling, difficulty breathing, feeling flushed or lightheaded, severe itching all over the body, nausea or vomiting, or breaking out in a rash or hives. If you experience any of these symptoms please notify the nurse IMMEDIATELY! We always have a physician present in the office in case a reaction should occur.
- We will provide you with a prescription for an Epi-Pen. This is an auto injector that is filled with Epinephrine or Adrenaline, which you would use in case a reaction occurs outside the office. If you feel you are having an allergic reaction, use your Epi-pen and immediately go to the emergency room. You will still need to seek medical attention after using the Epi-pen, as this can be a life threatening emergency. We recommend that you keep the Epi-pen with you in case of a reaction. Do not store the Epi-pen in your car as it is sensitive to temperature changes.

### **Consent**

I have read the explanation of immunotherapy and I or (my child) agrees to receive allergy injections and comply with the guidelines as outlined in this document. I understand that I am required to wait in the office for at least 20 minutes after every injection. In the event of a reaction to an allergy shot at the Center for Ear, Nose, Throat & Allergy, I understand I am responsible for any additional fees that are associated with the treatment of the reaction. I agree to hold harmless the Center for Ear, Nose, Throat & Allergy for any injury or loss I may experience.

Patient name (please print): \_\_\_\_\_

Date \_\_\_\_/\_\_\_\_/\_\_\_\_

Signature \_\_\_\_\_

Relationship to patient: \_\_\_\_\_