



Dalia G. Galicia, M.D.
Teri A. Lower, M.D.
Allergy, Asthma & Immunology
Hutchinson Clinic
1100 North Main
Hutchinson, KS 67501
1-800-779-6979 (620) 694-2060
Fax: (620) 694-2049

Allergy Extract CPT code: **95165**
Allergy Injection code: **95117**

CONSENT FOR PATIENTS RECEIVING ALLERGY IMMUNOTHERAPY (AI)

PURPOSE

Immunotherapy (allergy shots) are given to decrease the sensitivity of an allergic person so that exposure to offending allergens (pollens, dust, molds, etc.) will result in fewer symptoms. This does not mean that allergy shots are a substitute for avoidance of known allergens.

Allergy injections have been shown to lead to the formation of blocking antibody and a gradual decrease of the allergy antibody level. These changes allow the patient to tolerate exposure to the allergens with fewer symptoms. The patient in effect becomes "immunized" to the allergen. This immunization occurs to a different extent for each person.

INDICATIONS

The indications for immunotherapy are that there be documented allergy to substances in the environment that are unavoidable. Documentation can be either in the form of a positive skin test or a positive blood test (RAST). Symptoms such as hay fever or asthma should occur on exposure to the offending allergen. Due to the inherent risks of allergy shots, medical management should usually be tried first.

EFFICACY

Improvement should not be expected immediately. It usually requires 4-6 months, before any relief of symptoms is noticed, and 12 months might elapse before the full benefits occur. About 80% of allergic individuals on immunotherapy get significant improvement of their symptoms. This means that symptoms are reduced and not necessarily that they go away completely.

PROCEDURE

Injections are begun at very small doses as tolerated. The dose is gradually increased on a regular basis until the patient reaches a therapeutic dose (often called the "maintenance dose"), which varies from person to person. Shots are given at least weekly while the allergen dose is being increased. Shots may also be given twice a week during buildup to achieve the "maintenance dose" as quickly as possible. After the maintenance dose has been reached, most patients can receive injections every 2 weeks. The eventual goal is to spread the shots out to every 4 weeks over a period of several years.

DURATION OF TREATMENT

It usually takes 4-6 months to reach a maintenance dose. This time will be longer if there are allergy shot reactions along the way. The time will also be prolonged if the patient does not receive injections on a regular basis. For this reason, it is important that the recommended schedule be followed and that weeks not be missed. If it is anticipated that regular appointments cannot be kept, allergy shots should not be started in the first place. Patients who miss appointments frequently are at increased risk for reactions and may be asked to discontinue immunotherapy.

The length of time a patient continues injections depends on the response to treatment. Ideally, the patient should be free of symptoms without requiring medicine for about 1 year before the shots are stopped. The typical duration of treatment is about 3-5 years. Periodic appointments are scheduled to determine the frequency of injections needed. There are instances, however, when treatment may be continued beyond this time. Since the duration of, and changes in therapy must be individually tailored for each patient, regular follow-up visits are required.

RISKS

Allergy shots are associated with some widely recognized risks. This is because a substance that the person is allergic to is being injected into them. Most reactions occur within 2 hours of the shot.

Allergy shot reactions may include:

- a) Small local reactions (less than a half dollar) – common and not significant;



Dalia G. Galicia, M.D.
Teri A. Lower, M.D.
Allergy, Asthma & Immunology
Hutchinson Clinic
1100 North Main
Hutchinson, KS 67501
1-800-779-6979 (620) 694-2060
Fax: (620) 694-2049

- b) Large local reactions- also fairly common and of limited significance;
- c) Systemic skin reactions- uncommon. Not dangerous but suggest that more serious reactions may occur in the future if caution is not exercised;
- d) Systemic allergic reactions, such as wheezing, congestion, sneezing, runny nose or worsening of the allergy symptoms- very infrequent but of major significance if not treated immediately; or
- e) Anaphylaxis (severe allergic reaction) - rare but very serious and potentially life-threatening.

If one of the more significant reactions does occur, the medical care facility will have instructions to reduce the dose of the extract and buildup again slowly.

In general, about 30% who receive allergy shots will have a local reaction at some point during their course of therapy. Since a relatively large number of injections will occur during a 5-year course of therapy, no one shot is likely to cause a reaction. While most systemic reactions are not life-threatening if treated promptly, this fact does stress the importance of being in good health on those days when shots are given and remaining in the clinic for the required time. Less than 1% of patients on immunotherapy have systemic reactions. The estimated death rate is 1 in 2.5 million injections.

Due to the risk of systemic reactions, peak flows will be measured before and after each injection. The medical facility should have the ability to treat reactions that occur in the office; however, all patients are required to have epinephrine in the form of an EpiPen or Twinject and /or access to a peak flow meter. The injectable epinephrine should be available in case a reaction occurs after leaving the office. Instructions for its use will be provided. Ask if the instructions are not understood.

FEES

I understand that the Hutchinson Clinic charges a fee for production of allergy extracts. In addition, I understand that, there is a clinic fee each time an injection is given. Ask the clinic desk for the exact fees as these may change with time. Fees may differ at other medical care facilities. You should ask about payment policies at any facility before receiving shots there. Each allergy extract is made specifically for you and, once made; each vial can only be used for your allergies. If you receive your shots in another medical office, you will need to contact our office for each new set of vials. If you discontinue allergy shots prematurely, you will still be financially responsible for those allergy extracts which have already been processed.

INSTRUCTIONS FOR PATIENTS RECEIVING IMMUNOTHERAPY

1. Injections should be given at a qualified medical care facility. It is not recommended that allergy injections be given at home.
2. Patients should stay in the medical facility for a minimum of 30 minutes after each injection in case of an adverse reaction. The allergy shot nurse should check the patient before they leave. If a patient receiving injections in the allergy clinic leaves early, they will receive a warning at the next visit. After two episodes of leaving early, the allergy clinic will no longer administer injections to that individual.
3. Patients should report any current illness before allergy shots are given. In addition, a peak flow will be measured before and 30 minutes after each allergy shot.
4. All patients must keep their follow-up clinic appointments. At a minimum, patients should be seen in the allergy clinic at the least every 6 months or there may be a refusal to refill the allergy shot extract.
5. New vials should be ordered 1-2 weeks in advance of needing them, unless instructed other wise. Because there may be differences in the allergen content of a new vial, the first dose from any new vial will be reduced.
6. Please inform us if your medications change while on allergy injection therapy, this is especially important for blood pressure medicines, such as beta-blockers. Allergy injections may not be allowed in patients who receive beta-blocker medication.
7. Please contact our office immediately if you become pregnant while on allergy injections.



Dalia G. Galicia, M.D.
Teri A. Lower, M.D.
 Allergy, Asthma & Immunology
 Hutchinson Clinic
 1100 North Main
 Hutchinson, KS 67501
 1-800-779-6979 (620) 694-2060
 Fax: (620) 694-2049

INFORMED CONSENT FOR IMMUNOTHERAPY

I request the Hutchinson Clinic Allergy Department and/or my primary care doctor to administer allergy immunotherapy, also known as allergy shots over an extended period of time at specified intervals.

I understand that immunotherapy may result in complications of a severe systemic allergic reaction (less than 1% of patients) and even death (estimated rate of 1 per 2.5 million injections). The American Academy of Allergy, Asthma, and Immunology recommends that immunotherapy be given under a physician's supervision. This practice believes this position is medically appropriate and that you should always obtain your injection by trained personnel, either in our office or another medical setting. Thus, I understand that the immunotherapy is to be administered under a physician's supervision.

Furthermore, I understand that it is required for me to wait in the waiting room **AT LEAST 30 MINUTES** after each allergy injection. If I leave early, I understand that it is against medical advice and will hold my treating physician and the Hutchinson Clinic and their staff free of any liability.

In the event that I receive immunotherapy, I will notify the doctor or staff immediately if I have any allergic reactions to my injections so that proper treatment can be initiated. I understand that any time immunotherapy is given there is a rare chance of nicking a tiny blood vessel causing a bruise, numbness or pain. If there is swelling greater than the size of a quarter at the site of injection, I will notify the nurse or physician before receiving my next injection. About 30% of patients get a local reaction.

I understand that as a patient taking immunotherapy, I should not use Beta-Blockers because of the possible inability to treat an allergic reaction, including hypotension or shock.

I understand that if I have asthma, it should be under control when I receive an injection. If it is not, I will notify the nurse or physician before receiving my next injection.

I have been given the opportunity to ask questions about my condition and treatment, alternative forms of treatment, the procedures to be used, and the risks and hazards involved, I believe that I have sufficient information to give this informed consent. I acknowledge that this disclosure and informed consent has been fully explained to me, that I have read it or have had it read to me and I understand its content.

FEES

I understand that the Hutchinson Clinic charges a fee for production of allergy extracts. In addition, I understand that, there is a clinic fee each time an injection is given. Ask the clinic desk for the exact fees as these may change with time. Fees may differ at other medical care facilities. You should ask about payment policies at any facility before receiving shots there. Each allergy extract is made specifically for you and, once made; each vial can only be used for your allergies. If you receive your shots in another medical office, you will need to contact our office for each new set of vials. If you discontinue allergy shots prematurely, you will still be financially responsible for those allergy extracts which have already been processed.

Date: _____ Epi-pen Jr./Auvi-q 0.15mg: _____

Patient Name: _____ Epi-pen/Auvi-q 0.3mg: _____

Patient Signature: _____ Receiving shots at Hutch office: _____

If minor, Legal Guardian: _____ OR Other Office Address & Phone #: _____

Beta blocker: Yes _____ No _____

Glucagon Pen: Yes _____ No _____ First shot to be given in Hutch: _____

Asthma _____ Peak Flow Zones G _____ Y _____ R _____