

INFORMED CONSENT FOR SUBLINGUAL ALLERGY IMMUNOTHERAPY

The following information is for patients who may be considering sublingual allergy immunotherapy (SLIT) as part of their allergy treatment plan. With SLIT, *drops* or *tablets* are placed under the tongue for 1-2 minutes and then swallowed. This is repeated daily.

Currently, the only forms of SLIT approved by the Food and Drug Administration (FDA) are *tablets* for ragweed, northern pasture grasses and dust mites. Allergy *drops* are widely used in many European countries but in the U.S., they are considered investigational or “off-label” by the FDA. Because SLIT is not FDA approved, it is not covered by insurance.

The goal of immunotherapy is to reduce allergic sensitivities. The contents of allergy tablets or drops are based on your individual allergies. Allergy *drops* are started at a low dosage and gradually increased over a period of months until you reach a “maintenance” dose. The “maintenance” dose for an individual is one that achieves relief of symptoms without unpleasant side effects. Improvement of allergy symptoms will be gradual but the majority of patients on allergy immunotherapy will notice a significant reduction in their allergic symptoms. The duration of treatment varies and is individualized but the minimum period for most patients is three to five years.

Because allergy *drops* and *tablets* contain extracts of substances to which you are allergic, you and your doctor will need to be alert to any signs that you are having an allergic reaction to your SLIT. Side effects of SLIT are typically mild and include itching inside the mouth or stomach problems. Indications of a more significant reaction are described in the accompanying Immunotherapy: Frequently Asked Questions. If you begin to develop symptoms of an allergic reaction that you feel are due to your *drops* or *tablets*, please contact us. Because SLIT is a treatment administered at home with potential risk of an allergic reaction (albeit low), we do recommend having access to an epinephrine auto-injector.

Allergy *drops* and *tablets* should be given under the direct supervision of a physician, so that the physician can monitor potential problems and treat any reactions. If your allergic symptoms are not clearly improving, your provider may make changes in your prescription to make it more effective for you. It is important for patients who are experiencing persistent allergic problems to have regular re-evaluations. Patients who are doing well and have not developed any new medical problems should plan on a review of their treatment program with the doctor once a year.

SUBLINGUAL ALLERGY IMMUNOTHERAPY

Frequently Asked Questions

You or a family member may be considering sublingual immunotherapy. Patients frequently have questions about this form of treatment. Many of the most common questions are addressed below. Please feel free to speak with one of our staff members if your questions are not satisfactorily answered, or if you have questions other than what is addressed here. By working together, we will have the best opportunity for good results and improvement in your allergy symptoms.

What is immunotherapy?

Immunotherapy is a medical treatment involving administration of gradually increasing doses (in the case of *drops*) of an “extract” made from the allergens to which you are allergic.

Is every immunotherapy patient on the same prescription?

No. The allergy extract prescription is specifically designed for you, based on the results of an evaluation of your symptoms, medical history, physical findings and allergy testing. It is highly unlikely that two allergy patients will be on precisely the same extract prescription.

What conditions are treated with immunotherapy?

Immunotherapy is a preventive treatment for allergic respiratory conditions such as perennial and seasonal allergic rhinitis (“hay fever”) and asthma (“wheezing”).

What are the goals of immunotherapy?

The primary goal of immunotherapy is to relieve the symptoms caused by allergies. Immunotherapy should generally reduce your allergic sensitivities, thereby reducing symptoms and reducing the need for medications. Immunotherapy is not a permanent cure for the condition in most cases, but it usually will improve many of the symptoms and complications of allergic disease for many years.

How effective is immunotherapy?

Generally, the majority of patients who are receiving maintenance immunotherapy will have a significant reduction in their allergic symptoms, as well as a reduction in their need for medications.

What alternatives, in addition to immunotherapy, do I have for the treatment of my allergies?

Allergy problems are generally approached from three directions: (1) avoidance of recognized allergens; (2) medications; and (3) immunotherapy. Avoidance of the offending allergen is the ideal solution and is usually recommended for allergens such as foods, drugs and some animals. However, avoidance may be difficult when the allergen is airborne pollen or mold. Medications also may be beneficial, but only work with regular use and are most helpful when symptoms are mild.

Immunotherapy is a “long - term” preventive treatment that can alter the causes of allergic symptoms. It stimulates the patient’s immune defenses and is a natural response. A patient often will require a combination of avoidance measures, medications and immunotherapy for the most effective control.

Do I still have to avoid things to which I am allergic if I am taking allergy *drops* or *tablets*?

It always is wise to avoid known allergens, particularly easily avoided ones such as animals. However, many allergens such as pollen and mold are in the atmosphere and cannot be totally avoided. Very heavy exposure to an allergen may produce symptoms despite treatment with SLIT. Common sense is the rule, and heavy exposures should be avoided whenever possible.

Should I take allergy medications while I am receiving SLIT?

There is no interference between allergy medications and allergy immunotherapy. As you begin your immunotherapy, you should continue your prescribed medications because immunotherapy will take time to become effective. As you proceed toward “maintenance” immunotherapy, you may find that your need for allergy medications will decrease, and you will be able to gradually reduce or discontinue some of your medications. However, you should always talk with your provider before reducing an asthma medication.

How often will I take allergy *drops* or *tablets* and how long until they begin to help my symptoms?

Allergy *drops* and *tablets* are taken daily. The “advancement phase” may take several months. You should expect to begin seeing benefits from your immunotherapy as you reach maintenance levels, although some patients will require six to 12 months on a maintenance dose before seeing maximum benefit. Your dose should never be advanced if a significant reaction occurred after your previous dose. Exceeding the optimal dose can lead to worsening of symptoms.

What types of reactions or side effects might result from allergy *drops* or *tablets*?

Side effects of SLIT are typically mild and include itching inside the mouth or stomach problems. It is rare to experience severe allergic reactions while on SLIT but these symptoms would include:

- chest congestion or wheezing
- itching at any location
- abdominal cramping
- swelling of the tongue or throat
- hives
- light-headedness

Most serious reactions begin within 20 minutes but do not ignore these generalized symptoms even if they begin several hours after a dose of SLIT. These “anaphylactic” reactions must be treated promptly with injectable epinephrine. Because SLIT is a treatment administered at home with potential risk of an allergic reaction (albeit low), we do recommend having access to an epinephrine auto-injector (EpiPen, AuviQ, etc). If develop symptoms of an allergic reaction that you feel are due to your *drops* or *tablets*, please let us know as soon as possible.

How often do I need to schedule a follow-up visit with the doctor?

You should check with your provider on how often you need to be seen. Most often this is every 3 to 6 months the first year of immunotherapy and every 6 to 12 months thereafter if allergy symptoms have improved.

When should I have allergy testing done again?

There is no need for allergy testing every year. The general recommendation is that you consider getting re-tested every three to five years, or as new problems seem to develop. The doctor can discuss possible re-testing at your follow-up visits.

Should I inform the allergist of new prescription medications from other doctors?

Yes! There are several medications, particularly some blood pressure medications known as “beta blockers” that usually are not given along with immunotherapy. Please notify the nurse or physician of any new medications that have been prescribed for you since your last visit.

What if I become pregnant while on SLIT?

Allergy immunotherapy is believed to be safe during pregnancy. The only possible harm to your baby could occur if you have a major reaction with a drop in blood pressure and a need for oxygen. We encourage conservative treatment during your pregnancy and not advancing your dose above the maximum dose given prior to pregnancy. SLIT will not cause or prevent allergies in your baby. Please arrange a follow-up visit if you become pregnant so your allergy treatment program can be reviewed. One of the benefits of continuing immunotherapy during pregnancy is that you may need less of other medications.

SUBLINGUAL ALLERGY IMMUNOTHERAPY

Consent Form

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

Purpose

The purpose of immunotherapy is to decrease your sensitivity to allergy-causing substances, so that exposure to the offending allergens (pollen, animals, mites, 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 allergy medications.

Indications

To qualify for immunotherapy, you must be allergic to one or more environmental substances that you cannot avoid. You may have hay fever or asthma that occurs upon exposure to suspected allergens. Because of risks associated with immunotherapy, avoidance measures and medical management usually should be attempted first.

Efficacy

Improvement in your symptoms will not be immediate. It usually requires three to six months before any relief of allergy symptoms is noted, and it may take 12 to 24 months for full benefits to be evident. The majority of patients on immunotherapy note significant improvement of their symptoms. This means that symptoms are reduced, although not always eliminated.

Procedure

Allergy *drops* are usually started at a very low dose. This dosage is gradually increased on a regular (usually weekly) basis until a therapeutic dose (often called the “maintenance dose”) is reached. The maintenance dose may differ from person to person. Allergy *tablets* are started at the “maintenance dose” with no escalation period. Doses for both *drops* and *tablets* are taken daily.

Duration of Treatment

It usually takes one month to reach a maintenance dose for allergy *drops*. Most immunotherapy patients continue treatment for three to five years, after which the need for continuation is reassessed.

Allergy *drops* and *tablets* are associated with some widely recognized risks. The risk is present because a substance to which you are known to be allergic is being ingested. Life-threatening reactions are very rare with SLIT. Here are brief descriptions of the kinds of possible reactions, listed in order of increasing severity:

A. Local Reactions

Typically restricted to the mouth (itching, tingling) or stomach (nausea).

B. Generalized Reactions

Generalized reactions occur rarely but are the most important to recognize because of the potential danger of progression to low blood pressure and death if not treated. All generalized reactions require immediate evaluation and medical intervention.

Generalized reactions may be of one or more types:

1. **Urticarial reactions (hives)** include rash, swelling and itch 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 a dose.
2. **Angioedema** is 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 occasionally may be accompanied by asthma or difficulty with breathing and may progress to the most severe reaction, anaphylactic shock. In the absence of shock, the principal danger lies in suffocation resulting from swelling of the airway. Angioedema may occur within minutes after a dose and requires immediate medical attention.
3. **Anaphylactic shock** is acute asthma, vascular collapse (low blood pressure), unconsciousness and potentially death. This reaction usually occurs within minutes of a dose and is extremely rare.

The above generalized reactions are unpredictable and may occur with the first dose or after a long series of doses, with no previous warning. All generalized reactions require immediate evaluation and medical intervention. If a generalized reaction occurs, the immunotherapy dosage will be adjusted.

Observation Period Following First Dose of SLIT

All patients are expected to wait for 30 minutes following their first dose of SLIT and for the first dose of each subsequent new vial for allergy *drops* (every 3 months). Please bring your epinephrine auto-injector for these observation periods. If you have a reaction, you may be advised to remain longer for medical observation and treatment. If a generalized reaction occurs after you have left the physician's office, you should immediately return to the office, go to the nearest emergency medical facility, or call 911.

Pregnancy

Pregnancy Females of child-bearing potential: If you become pregnant while on immunotherapy, notify the office staff immediately so that the physician can determine an appropriate dosage schedule during pregnancy.

New Medications

Please notify the office staff if you start any new prescription medication, particularly medication for high blood pressure, migraine headaches or glaucoma. "Beta blocker" medications, often prescribed for heart diseases, are usually not allowed while on immunotherapy. Your physician will have to discuss with you the risk/benefit in these circumstances.

Questions

If you have questions concerning anything in this consent for immunotherapy, please direct the questions to the nurses or to the physician. If you wish to begin immunotherapy, please sign the Authorization for Treatment (Page 4).

**Consent for Sublingual Immunotherapy
 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 every precaution 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 sublingual immunotherapy (allergy *drops* or *tablets*) over an extended period of time and at specified intervals, as prescribed. I hereby give authorization and consent for treatment by Colorado ENT and Allergy staff, including authorization and consent for treatment of any reactions that may occur as a result of immunotherapy.

Acknowledgment of Financial Responsibility for Sublingual Immunotherapy (*drops*)
 Allergy *drops* are NOT covered by health insurance carriers.

_____ (Initial) I understand that allergy drops will be an out-of-pocket expense.

_____ (Initial) I understand that I will need to pay for allergy drop vials upon pick up. I understand each new vial will be a reoccurring expense (subject to change without notice). I also understand that typical treatment duration is 3-5 years.

 Patient Signature (or Legal Guardian)

 Date Signed

 Printed Name of Immunotherapy Patient

 Date of Birth

I will be receiving my observed doses of SLIT at the following location:

Audubon
 (Circle and Union)

St. Peregrine Pavilion
 (Woodman and Powers)

I certify that I have counseled this patient and/or authorized legal guardian concerning the information in this Consent for Administration of Sublingual Immunotherapy and that it appears to me that the signee understands the nature, risks and benefits of the proposed treatment plan.

 Eric Caplan, MD Jill Hanson, MD Morgan Dahms, PA-C

 Date Signed